Masterproef
Patient Outcome Measurement Tool (POMT)

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Master Thesis nominated to obtain the degree of Master of Management, specialization Management Information Systems
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Acknowledgements

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Introduction

Health care is the most prevalent and extensive social service known to human beings. Every person on this planet will one day come in contact with the health care system of the country of residence, from before they are born until even after the moment of death. The presence or absence of health care and the quality of that care determines not only the balance between life and death itself but also the quality of life for the approximately 7 billion people that populate our planet. Given the impact of health care and the enormous industry that exists specifically for this sector we can say that the health care system is a complex domain where many stakeholders interact with each other, where many funding sources are present and lots of interests need to be protected and safeguarded. From the governments to private insurance companies, from medical professionals to patients and their families, from pharmaceutical companies to sick funds, all these stakeholders have their vested interest in directing and steering the system in the direction that seems best for them in order to maximize the value they wish to obtain. Each of these stakeholders has in the end a motive and a strategy for pursuing their own interests inside the system and achieving the best possible results with the information and resources available to them. Some of these stakeholders are in search for a nice profit on their investments. Others, such as the government, are financing the system with their eye on the general interest of society and its citizens. Others aim for developing their products and treatments and even others are looking to receive the best possible care they can get with the resources they posses.

The government, as one of the most prevalent stakeholders in health care around the world, plays a key role in this health care system by providing legal, financial and organizational frameworks in order to create and/or improve upon, their health care systems. In the end their responsibility is to represent the voice of the citizens, to be the guardian of the people so as to provide the people with the best possible society based on their own cultural values. In the search for Universal Health Care, international institutions such as the World Health
Organization (WHO) specifically abstract themselves from pushing for one specific system because cultures and values differ around the world. Uniting these values in one system is an almost impossible and often unethical task, as it would mean stating one culture is ‘wrong’ while another is ‘right’. Nevertheless, general parameters of quality are essential in order to streamline health care delivery across the world and ensure it’s qualitative nature throughout the system.

These parameters of quality and progress are measured through collecting outcomes. An outcome is a form of data, something that can be measured and collected, something that provides us with insight into how effective and efficient interventions are and if there are complications resulting from those interventions or even from not having the intervention at all. The goal of collecting this information is to gain a deeper knowledge of what methods, products and treatments can be considered good and which ones can be considered bad. The concept of “Golden standard” is an important one in this context. Golden standards are descriptions of how procedures should be performed in order to achieve the best possible outcome for the best possible cost. It is the point that indicates equilibrium between effective treatment and cost of the treatment. Overall we can assume there is a positive correlation between quality of a treatment and the costs incurred for delivering a treatment. Obviously there are exceptions where the quality of the treatment does not correlate with the cost of the treatment. This could be the case for several reasons, of which we name a few here,

1. Inaccurate diagnosis of the specific disease image
2. Unexpected side-effects and/or complications
3. Pre-existing unknown conditions (e.g. allergies)

Now, what is good or bad in the health care context? In order to answer this question, patients and medical professionals are asked to complete certain standard questionnaires which are comprised of standard sets of questions and
can then be evaluated to come to a data set on which data analysis and data mining can be performed. The aim of analyzing these outcomes, the questionnaire results combined with the outcomes registered by the medical professionals, is to gain more insight in the effectiveness of a treatment and/or products used in that treatment. By analyzing this data, a insights can be established in order to further optimize treatment paths and products used for treatments.

Why then is it relevant to analyze this data? In order to start analyzing this question we need to look back a few years as well as a few decades, when the first building blocks of our modern health care system were being laid. Since the dawn of the financial crisis of 2009 and the resulting economic crisis, health care systems have been increasingly under siege by governments around the world. The new financial and economic realities call for a drastic reform in government budget spending. Their role consists in providing a legal and financial framework as well as direct public funding and interventions in private funds in order to provide adequate health care to citizens. However results have to be measured and data needs to be collected in order to able to optimize not only the outcomes for the patient but also the sustainability of the system itself. Therefore it is important to adequately define outcomes, what they are and how they are collected, so that we can come to qualitative data analysis for policy decisions as well as product choices and treatment options.

Outcomes are the driving force for evaluating health care systems, their efficiency and effectiveness and thus their financial impact. Measuring outcomes in itself can be a challenge because of among others, the intensity of work required for collecting data, the inefficiencies present in the current data collection methodologies and the selectiveness of data because of small sample sizes and discrepancies in collection methods and results.

Medical registries are phenomena that are coming more into the spotlight with the rise of information technology and its adoption in the health care context.
Medical registries are information systems conceived and developed with the goal of collecting outcomes in a way that eliminates all or most of the problems arising in the conventional data collection methods. Combined with integrated data analysis tools, medical registries can give useful insights in treatment effectiveness as well as product effectiveness and efficiency as a whole, both for the treatment and the product. Only in recent years medical registries have been found more useful because of new technologies allowing for adequate data gathering, storage, analysis and protection. Protection of data is a topic that deserves careful attention due to the sensitivity of the data being stored in these information systems.

The Patient Outcome Measurement Tool (POMT) is one such medical registry. It is an information system conceived, financed and built by Johnson & Johnson. Its aim is to provide an answer, and hopefully a part of the solution, to containing the rising health care costs. POMT aims to achieve these goals by providing the data necessary for optimization of treatments, optimization of products, clinical research and incentivizing medical professionals to collaborate and share information rather than keep it for themselves in ancient methods of data storage such as written documents and file cabinets.

We based our research on intensive literature study combined with regular interviews with Dr. Tomas Sorgeloose MD, MBA, MsC. Dr. Sorgeloose was the conceiver of the POMT and has been in the lead of the project from its conception to the current situation. These interviews were conducted by telephone conversations.

In this research we will aim to establish a framework of the current health care situation across the world. In chapter 2 we will try to identify the challenges the health care system is facing with special focus on problems related to data collection. Chapter 3 will discuss the concept of outcomes and why they matter so much. In chapter 4 then we will explain what exactly the POMT is, how it was conceived, what goals it is aimed to serve and how it operates. In chapter 5 we
will discuss how the POMT can help addressing the challenges we identified in chapter 2. Chapter 6 will then be an overview of our conclusions and how the future outlook is for the POMT.
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1 Health care systems

1.1 Health care systems socially explained

In order to discuss the influence of information technology systems on health care and the challenges societies all around the world face concerning their health care systems, we need to establish a framework of the societal role of health care and the financial systems driving health care delivery and management. In this chapter we aim to provide an overview of how health care systems are organized and composed as well as how they are financed through the various sources of funding. We aim to define and elaborate on the different stakeholders in the delivery of health care to individual patients, ranging from a surgeon to the government acting as the payer of delivered care, and see how they interact. In this analysis we focus on a few key countries with Belgium being given special attention due to the relevant domain of Belgium for the POMT system. Many principles and concepts of health care systems however can be generalized to most developed economies and even to some developing nations.

Health care can be considered as the most important social service a society provides to its citizens. From even before we are born we are already subject to the health care system of the nation in which our parents have their residence. People expecting a child are strongly recommended to go on routine checkups with a gynecologist from the moment they find out they are expecting a child. The gynecologist guides them from determining the pregnancy, the care given prior to birth (pre-natal), to the actual birth and finally the care that is given after the birth (post-natal). We call this sequence of procedures, checkups, interventions performed by medical professionals and spread over a certain period, in order to treat and monitor a patient concerning a certain disease image, a ‘clinical pathway’. This example of care delivered for a couple expecting a baby, shows just how essential and elementary adequate and qualitative health care is. From the moment we are conceived to the moment we die, we are in the
hands of a health care system that will determine, and is predefined by a range of parameters. These parameters include but are not limited to the following list:

- The type of care that is delivered,
- The accessibility of care,
- The quality of care,
- The speed by which care is delivered,
- The correlation between the accessibility and quality of care,
- The availability of health care professionals,
- The quality of the education and trainings of health care professionals,
- The financial impact of the care that is given, both on citizens as well as on the public funds (government) as well as on private funds (sick funds, private insurance companies),
- The quality of life of the patient receiving the care.

As the above statements show us, health care determines a broad and multi-faceted aspect of people’s lives by ultimately holding in its hands the most essential equilibrium known to all life on earth, that of life and death. If not deciding on this crude dichotomy, the conditions and rules by which healthcare is delivered determines the quality of life of every individual in any given system. Even its complete absence in a society determines life and death as well as the quality of life of the people subject to that particular system. We can think of the health care systems in sub-Saharan Africa, where health care delivery is lacking in nearly every way imaginable. Even when it does reach people needing care, the delivery of said care is often of poor quality due to several factors of which we name a few:

- Absence of appropriate and effective medications and antibiotics,
- Lack of access to hygienic and sterilized medical equipment and environments,
- Low quality of training and education for health care professionals,
Poor exchange of medical information, patient records and medical expertise due to lack of communication tools,

Ultimately the divide between rich and poor is reflected in the health care systems in some nations of the world. Especially in nations lacking Universal Health Care, this societal divide is easy to observe. The relatively tiny group of rich citizens enjoys qualitative health care thus improving their overall quality of life and life expectancy. Poor people however do not have access to the same facilities, hospitals or even doctors. They often rely on public health care that is of lower quality, lower availability and ultimately produces much worse outcomes. It is clear that the social divide based on income is symmetrical with the divide in access to health care in nations without Universal Health Care programs. Ultimately this symmetry can be expanded to state that the income divide is correlated directly to overall life quality and life expectancy, thus stating that poor people have a much higher chance of premature death than rich people, which can be considered to be a logical deduction.

From a social, humanitarian and moral perspective, health care services can be considered to be the most important social service a government can provide to its citizens. For most people in the world easy access to a fair, non-discriminatory, efficient and qualitative health care system is one of the most essential principles of a civilized and equal society in which there is no discrimination based on income, gender, ethnicity, sexual orientation or social status. Most developed countries with the odd exception of the United States of America provide some sort of Universal Health care for their citizens. It is in the end the goal of the World Health Organization (WHO) to fight for Universal Health Care in each and every country\(^1\). This does not imply all the nations of the world have to adopt this principle of Universal Health Care in exactly the same way and at exactly the same time. The WHO makes it clear that the concept of Universal Health Care has to be implemented according to the values, customs

and evolution of the nation itself. They themselves have to define how to get there and in what timeframe they want to get to a system of Universal Health Care.

Through Universal Health Care systems, governments aim to provide health care services to all members of society without social exclusion based on income and personal wealth. A government finds its reasons in providing universal health care by protecting their citizens financially, to provide adequate and qualitative care and to improve the overall health outcomes from chosen care paths. As an exception in the developed world the United States of America do not provide this type of health care to its citizens.

Instead they rely on a system of private insurance by which citizens with higher incomes have access to better care while those who are less fortunate have access to a basic health care service that is often inadequate for urgent medical needs thus influencing outcomes negatively. Both the delivery of health care, e.g. the hospitals and insurance companies, are private agents acting on behalf of their shareholders. These shareholders can be anyone willing to invest in these companies and searching for a healthy return on investment. This system has been the topic of much controversy among developed nations since many of US citizens have no or limited access to qualitative health care just because of their financial background. A reason for this behavior can be found in the organization of the taxation and economical system that is the very DNA of the economic system of the United States of America.

The people of the USA have always been known for their aversion to government intervention and taxation. At all times an individual should be able to pursue absolute freedom by showing entrepreneurial spirit, financial discipline and adequate insight in opportunities presented to him/her. This vision has led to a society where the pursuit for financial freedom has been highly valued implying tax benefits for those citizens who take risk to run a business and who work to establish it. The philosophy behind this system is that when companies and their
leaders are granted incentives in the form of tax benefits, they will stimulate employment through their blossoming business activities. In this way they create welfare and wellbeing for every US citizen while enriching themselves because of their entrepreneurial merit. The last few years following the financial implosion of the real-estate market in the USA have shown that this system is easily misused at the cost of the average middle-class citizens. In such a social culture of risk-taking, the poor are more or less appointed as to have only themselves to blame to be in the situation they are in, hence the tendency to restrict and resist government intervention. The financial crisis of 2008 however has given rise to doubts and challenges concerning the free-market system in which companies regulate themselves and thus create jobs and welfare. The collective bailout of many of the USA’s largest financial institutions such as Bear Sterns, Bank Of America and AIG has created a feeling of frustration and malcontent among those Americans who were hit the hardest in this crisis while they themselves were not the true direct cause of the crisis. Therefore reforms in health care are a very sensitive matter especially in those nations that were hit the hardest in the crisis that is still ongoing as of the moment of this writing. Following these societal and financial shifts governments are again crunching their numbers to look for any obvious opportunity to cut costs without hurting too much their political supporters and voters.

However, official government agencies all around the world have to adjust their calculations based on numbers that are increasingly becoming worrisome. With the rise of the financial crisis in 2008 health care spending has come under increased scrutiny once again as the original budgetary projections were no longer valid and being considered as way too optimistic. Under the new financial and economic environment countries that claim to have built a ‘social welfare state’ such as the member states of the European Union are reevaluating their social expenditures such as education, unemployment wages and the health care system because of the fact that these domains are the ones that consume the largest portion of the government budget. Other countries such as the United States of America, where public health care services is almost non-existent, are
making an attempt to close the gap between rich and poor by providing public health care for everyone through the ‘Patient Protection and Affordable Care Act’ of May 2010 now dubbed ‘ObamaCare’ after President Barack Obama (Democrats) who has pushed this act for affordable public health care for all US Citizens. However this particular initiative has fallen greatly behind on its initial conception and will only be enforced starting from 2014 due to political warfare in both the House of Representatives and the US Senate. Some effects however will be permanent even if the legislation does not make it through the political warfare in Washington.

Those economies that do provide universal health care provide public health care for all citizens no matter their wealth or income. Their governments have established redistribution mechanisms through the taxation system in order to capture income taxes from those citizens who are part of the workforce and place it in the social security system so that when a citizen requires health care they do not have to worry about paying significant amounts of money for the care they receive. In this manner discrimination between rich and poor is drastically reduced when it comes to access to qualitative health care. Not only is there a humanitarian and social benefit also the health outcomes and thus the effectiveness of the health care system improves.

There can be no doubt that access to qualitative and socially responsible health care is one of the essential corner stones of a developed society aiming for non-discrimination, openness and further development with taking into account core values and norms. We cannot ignore the social divide a privatized health care system creates by providing great health care to those who can afford it and lesser quality health care to those who can’t afford it. Health care should never be a matter of social division rather it should be a matter where we show our

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humanity in making sure our fellow citizens have the same qualitative health care as anyone else in society.

1.2 Health care systems financially explained

As one of the most important subsystems of every social system in the world, health care consumes a large piece of government budget in the vast majority of countries. Not only do governments provide financing through public health insurance, private insurance companies provide an additional service for those citizens able to pay for extra care and more comfort. Examples can include, access to a private room and more profound financial refunding after procedures. Both public and private funding sources are seeing that their expenditures are on the rise. Especially in nations belong to the economically developed world, such as Belgium and the vast majority of the European Union, the rise of health care costs as a consequence of demographic, technological and scientific evolutions is significant. Belgium’s health care system took up less than €1 billion in financing around the year 1970. In 1980 this figure had already risen to more than €3 billion. By the year 2000 the total cost of the health care system in Belgium amounted to around €12 billion. In 2010 the total cost of health care delivery was estimated to be around €24 billion. When looking at these figures one would be able to state that as long as the GDP grows relatively at an equal pace this growth can be considered sustainable. However this is not the case at all. When we compare the growth numbers of health care spending in terms of the Gross Domestic Product (GDP) we can see that health care spending, when considered over a time span of 30 years, rose annually at a pace of around 5%. Corrected for inflation this is still a vastly greater growth than the GDP growth in Belgium. It can be stated then that the growth of the health care spending is

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4 Ibid.
fundamentally unsustainable under the current conditions and government policies\textsuperscript{5}.

The ways and tools to deliver the promised budgetary balances are still under research but one thing is sure, ICT will play a major role in making sure the budget gap tightens. President Barack Obama even relied heavily on the further implementation and adoption of information technology to achieve his envisioned budgetary cuts of $516 Billion on the long term\textsuperscript{6}.

Health care is a domain that is financed and managed in different ways among different countries. The way the systems are financed determines the stakeholders that are involved. Universal health care relies heavily on public funding of the health care system, direct or indirect, while countries such as the USA rely heavily on private health care insurance to cover health expenditures. Even the exploitation of medical infrastructure and services, such as hospitals, is largely in the hand of private institutions. Public hospitals are funded by the state governments but lack in quality compared to the privately funded hospitals.

In the latter system the government is not, or very limitedly, charged with providing refunding mechanisms to the people who use health care services. Often we can see a mix of public and private funding in the health care system. This mixture of funding sources creates responsibility in multiple stakeholders while providing essential health care to all citizens instead of just for the privileged few.

As we stated before the financial crisis of 2008 and the aftermath following it have forced governments all around the world to adjust their financial budgets to fit the constraints they now face and try to attain a balance in the budget.

\textsuperscript{5} Ibid.
Budget cuts are being executed across the board and no sector is being spared from doing so. Given the financial budget of the health care sector which is often a large portion of government social security budget it is clear that governments, administrators, insurance companies and health care professionals will have to rethink and remodel the existing health care framework and organization.

Public health care expenditures are on the rise (source). All across Europe and in most other developed countries the financial and budgetary constraints are more present than ever and governments have no other option than to stick to these new parameters when composing the government budget. When we look at Belgium’s principal foundations of the health care organization, we can identify 3 main pillars.

1. Quality
2. Accessibility
3. Free choice

These pillars are currently under financial strain as health care costs are surging to ever-higher levels. Both public and private healthcare expenditures are rising and data shows that health care costs are rising faster than the economical growth7. Although politicians have an obsession with promising ambitious growth numbers for the GDP, the financial crisis of 2008 has changed every projection of expected GDP growth. This has led to governments having to revise their expectations of economic growth. The problem herein lies in that health care costs have not stopped growing. On the contrary, they are rising at an ever-faster pace due to demographic, societal and technological evolutions.

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1.2.1 Public health care funding

Health care funding comes from both public and private sources. Public funding comes through sick funds and social security provided by the taxpayers through taxation mechanisms put in place by the government. Citizens contribute to the social security system through both income taxation and other forms of taxation as well as direct contributions to sick funds. Sick funds are institutions put in place by the government to facilitate and secure refunding of medical expenses to its members.

When looking at the share of public funding for health care with respect to the total social security budget in 1980 the share of public health amounted to 22%. In 2009 this had risen to 35%.\(^8\) It is then obvious that health care is cannibalizing social security bit by bit. Especially in the last few years since the start of the global financial crisis this cannibalization has become more clear due to the budgets slimming down considerably and health care costs continuing their general trend of increase as the population gets older and medical technology changes to more individualized care paths. The demand for public funding has not slimmed down in any way, on the contrary. As the consequences of the financial instability, especially in the Eurozone where the European economies are confronted with several weakened economies and political indecision and/or contradictions, are becoming more clear the attention has refocused to bringing stability to the weak economies of Greece, Spain, Portugal and in some regard Italy. Because of the fact that the Euro contains several completely different currencies, stabilizing these economies is an incredibly difficult task with politics being afraid to take the necessary decisions and not having at their disposal to them one of the most powerful macro-economic medicines for economies in need, a devaluation of the local currency to stimulate export activities.

Even before 2008 the required effort for balancing health care budgets and ensuring health care delivery was already enormous. Now with the ailing economies it became even more difficult for governments to find budgetary means to ensure proper public health care funding and thus provide refunding to citizens in need of proper treatment.

### 1.2.2 Private health care funding

Private health care financing occurs in a complementary way to public funding. This however depends on the country and its health care system. Economies such as the USA have almost no public funding for health care delivery. The private insurance companies therefore are enormous corporations aiming to produce a healthy return for their shareholders, often being the topic of much controversy and political warfare. In other economies in the economically developed world such as those in Europe and Japan we see much more of a balance between public and private funding.

When we look at the Belgium specifically we see that 27.2% of the total health care expenditures are paid by the patient-citizens themselves (or his/her employer), so did the OECD calculate. These expenses can then be split up in ‘pocket expenses’ and ‘private insurance’. What is most remarkable is that there are only 4 OECD countries with a larger share of private expenditures than Belgium. These countries are the USA, Spain, Canada and Switzerland\(^9\). This is a remarkable fact given Belgium’s reputation for being a country with health care system that is almost free of any charges.

The rise of private health care expenditures however is not as problematic as the rise of public health care expenditures. Because private institutions have more

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flexible and easy access to capital funding through the mechanisms of selling shares to interested investors they can also anticipate and react better to a change in the health care landscape. Insurance companies have the agility of a private company while the government takes much longer to take decisive action. And even when decisions are made it is very likely the results will become only clear on a longer term. Private expenditures can thus be better controlled and adjusted to fit new evolutions in the health care landscape.

A normal citizen of a developed economy will thus rely on 2 sources of health care funding, public and private. For some countries the balance will tip more to public than to private. In many countries however the balance tips to the other side where there is more private funding through private insurance than there is government intervention in providing health services.

1.3 The role of government in health care funding

When reviewing abovementioned information one might question then what exactly different governments finance for the health care services specifically. Belgium as an example is known for its heavy tax pressure that is deemed necessary for financing the social security system of the nation. Many believe that Belgium is one of the countries with one of the most egalitarian health care systems where income makes no difference in the quality, nature and speediness of health care services received. Although the sick funds active in Belgium seem to be government-led institutions, due to their ties to political parties and thus government, they do not finance their refund activities with public funds coming from any of the many government present in the federal state of Belgium.

Belgium is among the countries with the highest stake of private health care funding for health care services although the perception is that the government pays for all of these services, which is clearly a wrong assumption. This is due to the fact that each Belgian is obligated by law to obtain membership of at least
one sick fund. In joining these sick funds the citizen commits to contributing a monthly fee to the sick fund in order to be insured either for medical assistance outside of the nation’s borders, which can be incredibly expensive, as well as for hospitalization in case of the necessity for a medical procedure or emergency intervention. These contributions are private insurance contributions made by citizens. This explains why we are among the few countries in the world that finance the vast majority of the health care system through private funds.

Then one might ask “What is the difference with insurers in the United States of America where delivery of health care services seem to be delivered in a much more unbalanced way in the sense that low income people receive poor quality health care while high income citizens with insurance receive high quality medical services?” This question is a just one as the USA is the OECD nation with the largest share of private health care funding, followed by Canada, Switzerland an in fourth place Belgium.

The crucial difference in this matter lies in the nature and regulation of the health care system. Insurers in the USA are not government assisted agencies but rather they are private companies, often traded publically on the stock markets and thus subject to the policy made by its shareholders and the profit targets accompanying this view. They do not necessarily only protect the interests of their customers, the patients, mostly they protect the vested interests of their shareholders which expect to earn a nice dividend on their investments. The sick funds as instituted in Belgium have the aim of acting as a pure redistribution mechanism so that all citizens can obtain refunds for their medical expenses through this mandatory health insurance. They are not lead by the interests of their shareholders, as they do not have any. In essence these sick funds have to answer to the government and most of all to its members. Members have the freedom to move from one sick fund to the other. This implies that the market for insurance is a competitive market although a few corrective mechanisms are at work preventing this market from being a true competitive market.
One such example is the political ties of sick funds in Belgium. All of the sick funds active in the Belgian market have some sort of political ties to a certain political party and/or political ideology. This has grown to be this way due to historical reasons. The Christian Mutuality fund for example is strongly linked to the Christian Democrats whereas the Flemish Neutral Sick Fund has some connection to the Flemish-nationalist ideology carried out by some political parties. The Socialist Sick Fund then again is linked strongly to the Socialist Party of Belgium. Members of political parties will thus be more likely to choose the according sick fund because of ideological reasons and not so much because of their financial refunding terms and conditions. This prevents the free movement of actors in this market.

Even though there is also an independent aid fund for disease- and disability insurance (HZIV)\textsuperscript{10}, most citizens in Belgium are member of one of the mutuality funds with political ties.

2 Challenges in the health care sector

2.1 Introduction

In chapter 1 we attempted to identify an overview as to how health care systems are organized, financed and managed. In this chapter we will attempt to identify and clarify the challenges that the health care sector is confronted with, ranging throughout the whole health care market. These challenges can be old or new, ranging over the whole scope of the market or focusing on just a small part of the market. We aim to create a clear framework for placing each of these challenges in their functional domain. Also, will we attempt to place priority in each of these challenges in order to identify the most urgent and essential domains in which effective action is required. It is important in this process to identify the connection between challenges as to how they interact and influence each other.

It’s clear that because of the shrinking budgets and cost-saving strategies of the players in the health care sector, have to reinvent their position continuously. In a market that is so rigorously regulated by legal frameworks and where the stakes are as high as losing human lives, it is important to clearly identify and define each role and the challenges that come with it.

2.2 Challenges in social organization of the health care sector

Being the most important social service provided to citizens, the health care system is confronted with a high sensitivity to demographic, cultural and lifestyle changes of the population. Also the economic organization of society is highly reflected in the health care system. Before the financial crisis of 2009, health care was identified to come under increasing pressure because of demographic factors such as ageing and the increasing number of people on the planet. The
social challenge throughout this story was to bring more equality in the three domains we mentioned above,

1. Access to care
2. Quality of care
3. Freedom of choice

Access to care is still lacking in many ways all around the world, even in highly developed economies such as the United States of America. In the USA for example, immigrants are proven to have less access to health care than do citizens of the USA. Even children of non-citizens have a lower degree of access to health care than do children of the same age born from citizens\textsuperscript{11}. This case only discusses the situation in the United States of America. When we take a further look on the situation, we see that people from third-world countries such as those in sub-Saharan Africa have almost no access to adequate health care services because of several reasons. These reasons include limited mobility and connected with this, geographical spread, as well as low availability of health care services in their region.

Combined with access to care, it can be shown that quality of care is another pillar essential for an equal health care system. Quality of care can be related to positive patient outcomes. A positive correlation exists between these two concepts. The higher the quality of the care delivered to the patient, the more positive the patient reported outcomes would be.

In order for a patient to be truly content with the health care system it is important the patient has freedom of choice of where the care is being delivered. The philosophy behind this aspect is that a patient should be able to determine which health care professional to choose according to his/her preference. After all the patient-doctor relationship often is a personal relationship as perceived by

the patient. The doctor is a trusted person that is entrusted with the medical and psychological history of the patient. Limitations to this freedom are related to the same parameters determining access to care. Geographical spread and thus limited availability of doctors reduces the freedom of choice of a patient and thus weakens the patient-doctor relationship, especially in third world countries, this is often the case.

Equality has become an even larger issue since the financial crisis of 2009. The perception of the financial crisis is that it was caused by the elite few, a handful of bankers, government members, industrialists, speculators and other members of international business, although the reality is quite more nuanced. It is this part of society that possesses the most wealth and thus has higher chances of being enrolled in a high quality health care insurance program providing effective and high quality health care services. The working classes in the USA and Europe have obtained the perception that health care should not be something only provided to those with wealth and power. On the contrary, health care should be available to all through taxation systems. This perception has only been enforced and strengthened with the financial crisis of 2009 when the media around the world extensively painted a picture of only a few in the world, “the top 1 percent” causing all of the financial problems. The reality however shows a lack of accountability on every level of society, where normal citizens never questioned cheap and easy mortgages and extravagant living standards.

We can see from these topics that the main challenge lies in providing an equal and fair health care system. The foundations of an equal and fair health care system thus would be,

1. Quality of care
2. Access to care
3. Freedom of choice
In order to obtain a universal health care system that provides health care services based on these 3 principles, to all citizens and not just the elite few, a financial taxation mechanism needs to be in place in order to redistribute wealth in order to finance the system.

### 2.3 Challenges in costs and financing of health care systems

An equal and fair health care system can only be sustainable when the costs can be controlled and the financing necessary for keeping the system going, is a self-sufficient mechanism that receives funds from both public and private funding sources. As we have discussed in the first chapter, health care systems are financed through both public funds as private funds. This mix of funding sources should allow for accessibility and quality. However, the mix itself and how the sources themselves are organized, will eventually determine the accessibility and quality of the health care delivery. We can easily illustrate this statement by comparing 2 health care systems that both have high degrees of private funding but have very different accessibility and relative quality parameters, Belgium and the USA\(^{12}\). Both of these nations have some of the highest degree of private health care funding but their systems differ in very drastic ways.

Belgium’s health care system is a system known in the world for being highly accessible for people of all income classes and of world-class quality. The health care system in the United States of America however is known for its discrimination based on the ability to pay for insurance and thus wealth. Then how can it be that two nations with similar private funding proportions are so different in the actual accessibility and quality of care?

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This is due to the fact that the private funds in Belgium are actually not completely private institutions at all. Each Belgian citizen is obligated by law to obtain a membership from one of the several mutuality funds that exist starting from the moment they either start working, reach the age of 25 or receive an unemployment fee. Children under the age of 25 and not meeting the other requirements are by law covered by the mutuality fund membership of their parents.13

So then how is the Belgian mutuality fund financed? They are financed through a mix of the contribution each member makes through either income tax, direct contribution fees to the fund and federal subsidies of the Federal Department of Social Security. Because the government is directly involved in first of all obligating every Belgian citizen to hold a membership with a mutuality fund and second of all by contributing subsidies directly to the different funds, the government actually helps regulating the entire private insurance market, which is made up of these mutuality funds or sick funds.

In the United States of America private insurance is a matter of privately held companies whose aim it is to optimize their operational results so that their shareholders can be satisfied with the results. The US government does not play a direct role in these insurance companies as they have privatized the sector of private health care insurance. ObamaCare tried to make a movement towards the Belgian model by obligating every US citizen to obtain basic health care insurance through government regulated programs. However this act has been the subject of much controversy, mostly coming from the Republican side of politics. The reason for this lies in the contradiction between either the striving for absolute freedom, for which the USA is famous, and government intervention in health care insurance.

It is important to have a basic understanding of how costs and financing are organized in the health care sector so that we can accurately identify and explain

the present and upcoming challenges for the health care market. If we want to accurately discuss the challenges in this market, we need to look at the problem from several perspectives.

2.3.1 Inflation in health care outpaces consumer price based inflation

Over the past few years, health care inflation has outpaced general economic growth and consumer price indices across the board\textsuperscript{14}. Health care costs are growing more rapidly than the growth of the economy. This is true for almost all developed economies in the world. Below we can see in Figure 1 that for the UK market, health care inflation has steadily outpaced the Consumer Price Index every year with the gap between them growing larger every year. This indicates that health care costs are not being contained and action is necessary in the short term.


Before the financial crisis of 2009, governments were already taking into account rising health care costs and were searching for solutions, be it more slowly. Since 2009 however, government budgets in the world economy have had to adapt to worsening numbers of the world economy. For health care this implies that the health care costs will have to be contained with an even smaller budget that is under far more scrutiny by all politicians involved. In the USA this health care reform is still a hot topic being even one of the key topics of the new presidential campaign of 2012. The Republican candidate has already committed to reducing health care spending for the lower classes of society meaning people at the bottom of society will even have a worse outlook for the future should this candidate be elected. They aim to introduce a voucher system aimed at controlling costs. However this system is clearly based on taking away health care spending for the poorest.

Obviously this is a controversial political position taking into account the current global economic situation. People all around the world are protesting against the

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fact that a few people in the world have so much wealth while the rest of the people have so little. Thus taking a stand benefiting the more wealthy classes of society, even more in a sensitive topic such as health care, can be extremely dangerous from a political viewpoint.

It is thus important to indicate the general trend in health care spending relative to the GDP of a given country. In the figure below it is clear that the total expenditure on health, as a percentage of GDP, is increasing in all of the countries that were analyzed\textsuperscript{17}.

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|c|c|c|c|c|c|}
\hline
\hline
Denmark & 9.1 & 9.3 & 9.5 & 9.7 & 9.8 & 9.9 & 10.0 & 10.3 & 11.5 \\
\hline
France & 10.2 & 10.5 & 10.9 & 11.0 & 11.1 & 11.0 & 11.0 & 11.1 & 11.8 \\
\hline
Germany & 10.4 & 10.6 & 10.8 & 10.6 & 10.7 & 10.6 & 10.5 & 10.7 & 11.6 \\
\hline
Netherlands & 8.3 & 8.9 & 9.8 & 10.0 & 9.8 & 9.7 & 9.7 & 9.9 & 12.0 \\
\hline
United Kingdom & 7.2 & 7.6 & 7.8 & 8.0 & 8.2 & 8.5 & 8.4 & 8.8 & 9.8 \\
\hline
\end{tabular}
\caption{Expenditure on health care as a percentage of GDP}
\end{table}

\textbf{2.3.2 Changing cost drivers in health care}

When attempting to identify what the true cost drivers in health care are, it is very difficult to establish a set of clear drivers. This is due to the fact that in such a complex and multifaceted domain as health care, correlations and relations among different drivers can be complex. When looking at this problem from a statistical point of view, it seems that there is no clear empirical evidence of what these real cost drivers should be\textsuperscript{18}. Medical professionals seem to be unable to agree upon this topic.


\textsuperscript{18} Ibid.
One of the possible cost drivers are the implementation of new treatments, procedures, medication and products. Under normal circumstances, one would think that these new developments would be bringing down costs. However this is not always the case. Let’s take one example.

Medicines are becoming ever more individual-specific. This is due to the fact that medical research scientists know the genetic code of humans to amazing depths. A new treatment can thus be targeted at the individual genetic code of the patient, leading to increased effectiveness of the treatment itself. Because we can find out the genetic code of every patient, custom medication, products or treatments can be designed to improve the patient’s quality of life; life expectancy and other patient reported outcomes. However, these treatments that have better outcomes, come at a higher price\textsuperscript{19}.

Another cost driver that can be identified is increasing patient expectations\textsuperscript{20}. Patients feel they are entitled to having a healthy life. This means that whenever they are confronted with a medical condition or problem, they will personally feel that they should receive the best possible care available without really taking into account the true cost of the care path necessary for giving them this optimal solution. Thus we can ask whether patients are entitled to a healthy life at any price. From a moral and humanitarian perspective we have to acknowledge that everybody has the right to accessible and qualitative health care. From an economic point of view we have to analyze the cost-benefit relation for any given care path, medication or other medical product. It is vital in this discussion to be able to determine best practices and golden standards not only on the short term but also on the long run. The basis for determining these decisions is outcome data over a large population, large enough at least to be able to draw accurate conclusions. Preferably this would be a mixture of patient reported outcomes and outcomes reported by medical professionals.


\textsuperscript{20} Ibid.
Is ageing then also a valid cost driver? There is much debate on this topic whether the ageing population is indeed a valid cost driver. We will discuss this in the section on demographics as a cost driver.

### 2.4 Demographical challenges

In this section we will consider some of the demographic challenges facing health care systems. Demographics have been the topic of much consideration mostly because of the logical correlation between an ageing population and rising health care costs.

#### 2.4.1 Ageing of the population in developed economies

The population of developed economies is ageing. People tend to have an increasing life expectancy and quality of life. This implies that when citizens retire from their working life, they can expect to live more years than they would expect to live a decade ago. As can be seen in the figure below, the percentage of the population over 65 years of age is increasing strongly ever since 2000 for Germany and more moderately for the other countries included in the study\(^{21}\).

This figure also paints a picture of what can be expected for the coming years. As the figure clearly illustrates, this percentage will increase ever more strongly, for some countries more rapidly than other, over the next 2 decades.

The ageing of the population implies that a citizen has more chances of more years of healthy life but also has the implication of a higher disease load in general. We can determine 3 domains where we see growth and also expect this trend for the future.

1. **Growth in chronic diseases**
   As people become older, also their risk of developing chronic diseases increases drastically. Examples of these types of diseases include: cardiovascular diseases, diabetes, arthritis, osteoporosis, dementia, Alzheimer and various types of cancer.

2. **Growth in multi-morbidity**

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22 Ibid.
24 Ibid.
Not only does the risk of getting a chronic disease increases as people become older, also their risk of developing more than one chronic disease increases significantly as they become older. 40% of people at an age above 50 years old in the European Union already show to have two or more chronic diseases\(^{25}\). A new study that is still ongoing in Newcastle is showing even more astonishing results. In this study it is claimed until now that out of a population of 1000 people aged over 85 years, they show on average to have 5 chronic diseases\(^{26}\). Statements such as these imply that the need for medical assistance and thus medical costs increase dramatically when crossing the age of 65 years. This presents enormous challenges to the health care system unless drastic measures are taken in order to control costs better. One of the measures undertaken in some member countries of the European Union, such as Germany and The Netherlands, is to increase the age of retirement to levels in which the benefits of additional taxes outweigh the additional costs of an ageing population.

3. **Growth in the demand for social care.**

As the population grows older and more chronic diseases turn up, the need for social care will increase as well\(^{27}\). Social care can be looked at as an activity or a set of relations that can be found in the overlapping of market, family and state\(^{28}\). It is the care given to people in unfavorable financial conditions, those who cannot afford health care for themselves. Social care can be either paid or unpaid. At the center stands the concept of taking care of others, be it for direct or indirect benefits and merits. An ageing population implies more elderly people falling back to being on their own after losing their life partner, increasing cases of losing family in the process which topples the traditional view of coherent family

\(^{25}\) Ibid.
\(^{26}\) Ibid.
\(^{27}\) Ibid.
structures where elderly people never got to see the moment their younger family members pass away or move on with their life in a different direction, such as divorce. Combining the ageing of the population with the growing economic turbulence, a widening dichotomy between rich classes and poor classes, implies the need for social care will only increase in the future.

2.4.2 Lifestyle diseases

As the research of Kielstra (2011) illustrates, an ageing population will have a growth in chronic diseases as a consequence. However we cannot state that ageing is the sole cause of this rise in chronic diseases as well as the rising multimorbidity. Unhealthy lifestyles are a major driver of chronic diseases. These unhealthy lifestyle habits include smoking, alcohol consumption, obesity and lack of exercise coupled to increasing sedentary lifestyles. Governments in Europe are taking ongoing efforts of prevention towards smoking by including explicit warning messages on cigarette boxes, prohibition of public promotional tools such as add boards. Concerning alcohol, the government put in place mandatory warning messages encouraging sensible consumption of alcohol as well as enforcing strong legal consequences for public intoxication and driving under the influence of alcohol.

However when looking at obesity, the government cannot take the same steps as they do with smoking and alcohol. Obesity poses a serious issue for the next generations as people are becoming increasingly sedentary and involved in unhealthy eating habits. The readily availability of fast food and frozen meals have not helped with this evolution.
As the table above illustrates, the percentage of people dealing with obesity is alarmingly high, especially in the UK where we can see an obesity rate of 61% of the population. This evolution is extremely alarming, as people, who show high exposure to bad lifestyle habits, tend to have much more chances of developing chronic diseases and also multi-morbidity. People who are obese over a longer time period have a very elevated risk of developing diabetes later on in life, for example.

### 2.5 Competing demands in health care

In health care there exists the position that the new generation of medical professionals and financing institutions will together have to decide upon the cost-effectiveness versus equality. We discussed earlier that optimally, taking into consideration humanitarian motives, health care should be accessible to all as well as of the same quality for all, no matter the wealth of a patient. The comfort however can be the topic of discrimination, as it does not directly influence the patient outcomes.

30 Ibid.
2.6 Attachment to existing systems

Often the mentality of stakeholders in the health care system was “if it isn’t broken, don’t fix it”. Because of the involvement of human lives, stakeholders were often reluctant in taking drastic measures to reform health care. This meant these stakeholders held on to the existing systems. However, recent economic developments are forcing these stakeholders to reconsider health care, as the current financial evolution of health care is completely unsustainable, given the growth of health care costs relative to GDP.

2.7 Complexity

Health care systems are among the most complex societal systems in the world. Because of the involvement of so many stakeholders with each of them carrying very different motives and ideas on what the perfect system would look like, the system as a whole is like a “shoal of fish that swim like a whale”\(^\text{31}\). Decisions should be taken more rapidly and more effectively.

2.8 Focus on prevention instead of reactive treatment

Health care should no longer be only about providing care in a reactive manner, as is largely the trend in the current systems, especially in those in third-world economies. This way of seeing health care needs drastic reform as health care should start looking more to actively working on prevention instead of reactive care\(^\text{32}\). By focusing largely on prevention and less on reactive care, patients will


not end up in the hospital in the first place. It is better to catch diseases and conditions in the house physician practice than by sending patients immediately to the hospital. Detecting conditions and diseases early on in the disease process or even stimulating healthy lifestyles, will drastically improve patient outcomes. The challenge herein lies in how to collect adequate data for improving prevention efforts. Prevention can come from predicting possible side effects and anticipating on them efficiently and upfront instead of reactive care.

It is clear that the challenges for the coming decades are enormous and need to be addressed today or at least be given a good start to. Over the next few years governments and other stakeholders will have to make decisions that will affect the lives of their citizens in ways we cannot describe accurately. People’s lives depend on the health care system being able to follow the general trends of challenges.

In the next chapter we will discuss medical outcomes reported by both medical professionals and patients themselves. In order to take accurate and efficient decisions on the future of health care, stakeholders in the health care sector must have access to relevant and qualitative data. Medical registries, such as the POMT, use outcome data as input and aim at collecting, optimizing and sharing this outcome data.
3 Outcomes and outcome measurement

3.1 Introduction of concepts

In order to analyze and understand the problems we aim to discuss in this paper, it is of importance to define and explain a range of the medical terms in the domain of outcomes measurement and management. A selection of terms relevant to our discussion can be found below.

**Outcomes or Outcome Measures** in a health care context can be defined as “Health care quality indicators that gauge the extent to which health care services succeed in improving and maintaining satisfaction and patient health”\(^{33}\). The term outcome can also be explained as “A tool to assess the impact of health services in terms of improved quality and/or longevity of life and functioning”\(^{34}\). A definition of the term ‘Outcome’ itself is an ongoing topic of debate within the medical community.

**Clinical Outcome** – “The result of medical or surgical intervention or nonintervention, or the results of a specific Health care Service Provider (HSP) or benefit package. The valued results of care, as experienced primarily by the patient, but also by physicians and all other participants in the processes contributing to the outcomes”\(^{35}\).

**Outcomes Measurement** – “A System used to systematically track clinical treatment and responses to that treatment”\(^{36}\). The author continues in stating


\(^{34}\) Ibid.

\(^{35}\) Ibid.

\(^{36}\) Ibid.
that the method for measuring varies among providers. Agreement on best practices and tools to handle measured outcomes has not been achieved.

**Health Care Provider** – “Providers of medical or health care or researchers who provide health care. Normally health care providers are clinics, hospitals, doctors, dentists, psychologists and similar professionals” 37.

### 3.2 Outcome measurement defined and the benefits of conducting measurement and management.

Outcomes are bits of data, either reported by medical professionals, patients or other stakeholders involved, that reflect the effectiveness and efficiency of a given treatment, product or care path. It is important to measure these outcomes of medical care although this remains a challenging part of clinical research. Quality improvement and mechanisms for monetary incentives to medical professionals depends on the accuracy of outcomes and the conclusions that can be taken out of them 38. In this research, performed by Dassow (2007), we are obliged to point out the strong emphasis on the health care context of the United States of America (USA). The manner in which the above-mentioned financial incentives are applied depends strongly on the financial construction behind each health care system. A distinction between the USA and continental Europe is of importance for the correct assessment of financial incentives and their impact.

Monetary incentives are often used as a means to force accountability and/or responsibility of people operating in a certain domain. For medical professionals, this accountability and responsibility takes a more important position in the daily

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37 Ibid.

execution of their job. Within their profession, medical professionals are responsible and accountable with regards to their patients by means of always searching for the optimal care path with the aim of curing their patient. The physician, under assumption of a normal functioning physician, obtains a sense of caring for a patient, which leads to a natural feeling of accountability and responsibility. In many cases, the life of a patient is literally in the hands of the physician. When it comes to dealing with clinical research however, accountability and responsibility are a more abstract concept. While testing new medicines, new medical devices or other equipment necessary for composing care paths, the physician does not have responsibility over one particular patient but instead is searching for the optimal solution for patients as a whole and thus also has to take into consideration their own ease-of-use and the cost-benefit relationship of a particular product. After all financing needs to be found and the cost-benefit relationship must be optimal as a requirement to receive approval and financing.

What the payer is hoping to achieve with monetary incentives is to bring more accountability and sense of responsibility to the medical professional in the domain. Of course it cannot be ignored that the core motivation behind monetary incentives are to provide more cost-efficient procedures, products and treatments in order to control the costs of health care while optimizing quality of care delivered.

Indeed, medical professionals are responsible for asking the right questions and ensuring correct data extraction during their contact with the patient. Monetary incentives are one of the available strategies to stimulate cooperation and correct extraction of data relevant to the clinical path. Outcome measurement, when the outcomes are well designed and defined, creates three main benefits for non-profit organizations according to Rublin\textsuperscript{39}. These benefits can be linked to other

organizations and institutions using outcome measurement to optimize the organizational processes.

First, outcome measurement helps an organization measure the success it has. This includes identifying important problems, registering the quality of the services offered and motivate the staff so that services can be optimized continuously. Effective performance measures can revitalize an organization, reflect and optimize focus domains and resource allocation. It also is a communication form to all the key stakeholders of the organization to present a picture of where the organization, market or institution is heading. In the health care market, this is as valid a point as it is for non-profit organizations, even more so in fact. The fact that results are continuously being tracked, analyzed and reviewed for improvement areas, means that the medical staff carries a heavier sense of responsibility. Mistakes can be tracked more rapidly and thus corrective action can be taken. In the health care context this can impact people’s lives in profound ways such as improvement of Quality of Life or even the difference between life and death. Continuous improvement is a key focus point for any organization, especially for health care providers.

Secondly, it aids in allocating resources more efficiently in order to optimize the performance and impact of the organization. Especially in a time of scarce resources and focus on reducing footprint, this can be a critical process for any organization. Further benefits can be found in the capacity to streamline programs or product lines, find the areas where operations should be scaled back and thus find cost savings while not harming effectiveness. Applying this to health care, we can state that treatments can be considered in a more effective way. The medical professional already has outcomes of similar conditions or procedures and thus knows what outcomes may be possible. If the data set is large enough to produce valid sample sizes, there can be a more effective and efficient evaluation of the allocation of resources. This could imply that some procedures would be recommended where in the past they were not considered as well as preventing ineffective procedures to take place. It is a paradigm shift
from a combination of “shooting in the dark” and “calculated trial & error” to “targeted treatments”. This will lead to more effective treatments, use of products and care implying a reduction of costs in the long run.

The third and final benefit is that outcomes measurement helps the organization to be more competitive in obtaining funds\textsuperscript{40}. In the case of the medical industry, both public and private funds can be more easily obtained when the stakeholders hold in their hand adequate and valid outcome data to base certain budgetary decisions on. This point is made from the point of view of non-profit organization. Applying logical deduction, this benefit can be interpreted for the health care sector as such that when outcome measurement is optimal, we will see an optimal allocation of refunds for medical care from the payer as well as subsidies for the development of new medicines and medical products. Governments and insurers are increasingly asking for accurate information on the chosen care paths, products and medicines. In order to help bring budgetary clarity for governments and insurers, outcomes data will serve as an important driver for decision-making and strategy orientation.

According to Kane, R. (2004)\textsuperscript{41}, outcome analysis in a health care context can be done because of many reasons. The first reason the research describes is “to make market decisions”. Patients may want to have an idea of how good their treating physician or clinician has done his or her job in treating their problem. This also applies to those acting on behalf of the patients. Also medical companies want to be able to make better decisions concerning their products and future strategy options.

The second reason for outcome analysis is “for accountability”. Medical care involves several stakeholders who each have to gain or to lose. Therefore the


quality of the delivered work is of crucial importance. Especially the payers need
to ensure the care provided is of sufficient quality.

The third and final reason Kane (2004) describes is “to improve the knowledge
base of medicine”. This reason can be easily explained by what Kane (2004)
states as “the substrate for evidence-based medicine (EBM) is good evidence on
which to base [the knowledge base of medicine] it. Solid outcomes information is
the crucial building block for the EBM\footnote{EBM = Evidence-Based Medicine. EBM is the methodology of treating patients based on best practices that are established through performing large clinical trials. Retrieved from http://orthomolecular.org/resources/omns/v07n15.shtml} edifice.” More solidly imprinted in the
medical community are randomized controlled trials or RCT’s. Outcome research
is not meant to be a substitute for RCT but rather a complement. Outcome
research aims to capture a particular piece of knowledge in the medical domain,
which is “a better understanding of how treatment in the real world affects a
wide range of outcomes”.

Kane goes on further to discuss the reasons why clinicians have difficulties with
outcomes and registering of outcomes. Some of these reasons, we discuss here
briefly.

\textbf{1. Not all the outcomes are under the control of the clinician.}

Because outcome registration and measurement is a collaborative work of
individual clinicians or larger health care organizations, the failure of the
system is just as harmful as an individual error. Also, other factors besides
medical care influence the favorable outcome clinicians aim to achieve by
applying treatments. The variance in outcomes is not completely to be
explained by treatment decisions and applications. Kane (2004) puts it
concisely as “one can change the risk of a successful outcome by several
orders of magnitude by interventions that fail to explain even a modest
amount of the variance in outcomes”.

\footnote{EBM = Evidence-Based Medicine. EBM is the methodology of treating patients based on best practices that are established through performing large clinical trials. Retrieved from http://orthomolecular.org/resources/omns/v07n15.shtml}
2. **According to the theory, outcomes and process measures should be closely linked but practice shows that “the correlation between process and outcomes is often weak”**.

This result implies logically that a bad outcome is not necessarily an indication that things should be done in another way. Outcomes can only be regarded as the first step of an investigation so that people concerned with the matter know a bit better where to search concerning the process of care. An indication of where to look for the root problem is all bad outcomes can be.

3. **Collecting outcomes information requires more effort and thus creates extra expenses.**

“Medical record keeping is notoriously inconsistent” as Kane (2004) describes based on research by Weed (1968a, 1968b). Much of the documentation and information is based on judgments in which even definitions are not always consistent. Often it is also the case that data is incomplete and thus the outcomes are influenced. A lack of systematic information is present, as physicians not always see patients returning to their practice after care has been given. Patients could move or change physician. In these cases crucial information, sometimes even more relevant information than that of patients who do return, is spread over several databases of several physicians. Also, information on variables that have an influence on outcomes is not systematically collected.

4. **“Outcomes are essentially probability statements”**.

As discussed in the previous statements, a wide range of factors influences outcomes. Sometimes they are factors that are not registered correctly or not at all. Outcome information therefore should never be seen for an individual case. What makes this information relevant is the law of large numbers. The more outcomes collected, the better it will give an indication for investigation or action. The experience of the clinician plays a significant role in assessing outcomes and collecting them altogether.
5. **Outcomes can only be analyzed with acceptable confidence levels when the size of the sample is large enough to be significant.**

Because outcome analysis relies on having enough group data to generate a significant sample, it can sometimes be difficult for individual clinicians to gather enough data for a particular condition or disease image. Rapid aggregation for analysis is thus hindered which results in the outcome analysis itself being unacceptable. Two strategies are known to Kane (2004): either data on cases is collected over a timespan of several years or by means of group collection through the collaboration of clinicians. Each of these approaches carries their own advantages and disadvantages.

6. **“Outcomes take a long time to assemble”**.

The first step is that we have to gather enough cases in order to correctly define outcomes. Then for each case, we have to gather enough data for the outcomes to become apparent. This implies that by the time the results can be published, the selected care happened a long time ago and therefore, the results are no longer fresh. However we cannot ignore that measurement is needed for furthering clinical research and provide best practices for procedures and products.

So how can outcome measurement actually contribute to solving the problems of increasing costs in health care? Those stakeholders who carry the majority share of the costs of medical care (government, mutuality funds/insurance companies) are increasingly seeking methods and tools to manage and control care paths of patients with a focus on controlling costs.

Incentives can be found in several places. We see the populations of Western Europe, and with them other industrialized nations, ageing in an ever-faster
Demographic predictions, as shown in figure 5 below, indicate that the life expectancy is still rising steadily. Where in the past people often died at a younger age, such as in their 60’s, now because people are expected to live up until around 81 years, people are increasingly showing chronic diseases related to old age and lifestyle effects over the long term. Diseases related to old age include among others diabetes, kidney failure, cardiovascular disease, cancer, Alzheimer and arthritis.

It is no secret that, in 2008, the industrialized world has gone through one of the biggest financial crises since the Great Depression of 1929. Even today the economies of continental Europe and the United States of America are still in crisis with the partners in Asia and South America experiencing a slower growth than previous years. Governments and regulatory bodies are struggling in finding the right medicine for the illness that has taken the global financial markets.

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Governments in particular are faced with the need to cut down costs in order to make up balanced budgets that will address the structural challenges for the next generations.

Shrinking budgets and the increased need for transparency towards the patient, the payers, the regulatory bodies and commissions are leading the discussion in order to achieve the goals that were set forth. Not only do the increasing health care costs affect government institutions, insurance companies and health care providers, also the medical and pharmaceutical industry is affected. Manufacturers of prosthesis, suppliers of medical materials, such as Johnson & Johnson, are being requested to clarify their clinical processes and enhance transparency in the development and production of their products.

Under normal circumstances, with the abstraction of emergency procedures, a patient comes to a physician or hospital explaining their situation. Patients report pain, nuisances, feelings of uneasiness which, once combined, resulted in treatment and diagnosis being developed through the parameters and variables observed by the physicians, surgeons and care providers. Patients allow the professional medical staff to observe them, perform tests and investigations in order to establish a diagnosis that comes as close as possible to the suspected root cause of the reported problems. These parameters and variables are the “gold standard” for medical staff, which in their view provides them with sufficient information to determine a complete treatment path for the patient without the patient ever having to be really involved in coming to this result. The patient reports, listens and follows the guidelines written out by the medical practitioner.

A new approach to this model has developed. Medical industry professionals and care providers realize that the only true ‘outcomes’ stem not exclusively from the opinion or experience of a medical professional. Better outcome measures come from the patients themselves. A patient does not only have pain or symptoms of a disease or infliction. Patients have values, principles and have a much better
understanding of their own condition, their history and their preferences. More importantly, patients have better perception of the variables determining the outcome measures. Patient delivered information and indicators take away the problem for the physician of having to work with a certain moment recording. The patient should be involved in registering and following up on their own care path so that medical professionals obtain a continuous image of the patient. Not only are these clinical variables more relevant, they are also more meaningful, more valid and less expensive to obtain (Fries 2005)\(^\text{45}\).

One of the ways of obtaining these key patient indicators from the patient is through the usage of questionnaires. Questionnaires offer a way of obtaining information from patients by asking specific questions. These questions are implemented in a dynamic application in which the questionnaire evolves as it develops. Questionnaires can be either digital, paper-based or through the usage of survey techniques. The data that these questionnaires produce are registered and stored in databases, which are in essence item banks or registries. The aim of these registries or item banks is to perform data analysis and achieve statistically powerful indicators and patterns with less input and thus less costs, reducing complexity, redundancy and inefficiency in the process.

Developing item banks or registries is a complicated and labor-intensive task. Qualitative item review and improvement must precede data analysis and the resultant computational and statistical analysis. To develop an item bank that enables short, efficient and precise assessment, lengthy preparation is necessary. A domain model must be conceived and analyzed (Fries & Bruce 2005)\(^\text{46}\).

It shows that capturing outcome measurements, which are usable, cheap and yet powerful and relevant, is not an easy task. Intelligently developed questionnaires


\(^{46}\) Ibid.
can go a long way in reducing cost overhead, reducing wasting mental capacity and effort and reducing error tracking and defect repair.

Outcome measurement is a domain in health care, which stretches to all possible stakeholders. Each of these stakeholders have vested interests in making sure outcome measurement happens in a qualitative, quantifiable and efficient way. It is no secret that since the financial crisis of 2008 governments are seeking to significantly cut their budgets in order to respond to the growing insecurity and an atmosphere of panic that dominates in the global financial markets. The dramatic consequences and aftershocks of the financial crisis are still present in the world economy and they are putting intense pressure on policy makers and institutions. In the European Union, the European Commission is demanding that its member states uphold budgetary discipline as well as reform and restructure their social security systems. These requirements and policy guidelines are necessary should the welfare states of the European Union be able to continue to meet their social obligations towards their citizens. Not only is this an issue for today, it is also one for the future when the current young working generation will be needing the social facilities provided by the state government.

Budget cuts are happening in every domain, from education to migration, from industry to financial institutions. Health care is no exception. Health care cuts, however, cannot be approached in the same way as other budgetary cuts. As we have established before, costs of health care are rising increasingly and there is no halt in sight to this evolution. Governments and insurance companies are facing an enormous challenge to rethink the existing models of health care financing by implementing new IT systems based on technologies that will allow them to cut costs while improving quality and availability to all stakeholders.

Possible measures in controlling social security and health care costs do not indicate reducing the social benefits and facilities of patients. Efficiency and effectiveness are the vehicles that will bring down costs and reduce the stranglehold on many governments’ budgets in the process. The implementation
and usage of Information Technology is a large part of the engine of this vehicle that will make it possible to improve health care for all patients, increase citizens’ access to care and facilitate quality of life increases for everyone. Budget and cost reduction should only arise through the use of more efficient measuring, more proven care paths, more efficient integration of ICT in the medical sector, both in medical companies, insurance companies, practitioners, hospitals as well as through the coupling of these systems with the government. Transparency should not be regarded as a threat of revenue losses but as an opportunity to enhance the organization as a whole on the long term and thus gaining competitive and strategic advantage. Outcome measurement lies at the heart of this evolution. Systems such as POMT, which aim not only to capture this valuable data but also to analyze and process the data, will have a significant role to play in establishing golden standards, optimizing the complete care path performance and effectiveness for patients and stimulating knowledge sharing.

3.3 Information technology and the trends in the industry

Since the dawn of the Internet, it has given way to trends in digital information processing and sharing. Recent trends include distributed computing, in which the computing of several computers is combined inside a networked environment to gather the superior aggregate computing power and thus perform complex computations in less time. Another trend is digital distribution, in which software and media is distributed through the Internet or any other network of computers as digital downloads. A physical medium such as CD, DVD or even Blu-ray is no longer required. The rise of high-speed fiber-optic Internet connections was the main infrastructure technology to facilitate this evolution.

A third important trend is the sharing of personal information, our digital identity. Because of the availability of many pocketsize communication devices that rely on constant connection to the cellular networks, the Internet has become readily available for individuals who wish to share their information. This
information can be purely professional but even more popular is sharing our personal information through social media. Social media are the first applications to capture the potential of sharing personal information in ways that weren’t possible in the past. However this evolution has not gone without risks.

These developments in sharing of information have brought about many privacy and security issues. Facebook, for example, is constantly under attack from the Internet community as it has facilitated anyone on the Internet to be able to access personal, and often private, information such as pictures, family information, connections to others⁴⁷. Not only can others access individual’s personal information, Facebook has even gone so far as to allow third parties to gain information of its users. Twitter, a digital platform for sharing short messages of no longer than 140 characters, has faced major security issues as recent as 2009 by which a malicious user could insert JavaScript code into their Tweets in order to channel malicious software to unsuspecting users⁴⁸. Obviously Twitter Inc. responded quickly in order to address this issue but still it proved that no system is truly safe when faced with usage by many different users.

These cases prove that security in information technology is a domain for constant attention and investment. Especially in the medical care sector, when dealing with private medical information of millions of patients, privacy and security ought to be the primary concern of system developers and integrators alike. Later in our discussion we will address the major issue of privacy and security.


Let us return to our discussion of the role of information technology outcome measurement.

### 3.4  Information technology and outcome measurement

As we have stated in our discussion above, it is necessary for medical professionals to allow the patient to co-manage their individual care paths together with their physicians. By involving the patient in this way we will obtain more relevant, less expensive and more qualitative key patient indicators that will ultimately lead to a better treatment outcome. This benefits the patient, by means of an improved Quality of Life (QOL), as well as the treating medical professionals, by means of improved patient satisfaction and quality of life.

We stated that one way of obtaining relevant outcomes of patients, information that truly affects the patients’ quality of life, is by using logically constructed questionnaires. In the past, questionnaires were often in paper form. A physician filled in the papers by asking the patient the questions that made up the questionnaire. After completing the form, the questionnaire was added to the medical file of the patient. When undergoing treatment or a procedure, the questionnaires could then be taken again and results could be compared. The problem here lies in the fact that there was no way of applying complex analytics and regression analysis without using labor-intensive methods. With the advent of the digital age, this has completely changed. Computers, mobile Internet devices and high-speed Internet connections are now widespread in those parts of the world where the POMT is rolled out or will be rolled out in the future. This evolution has made way for the easy accessibility of web-based information systems and thus patient involvement possibilities.

Medical professionals don’t have to spend time anymore taking the questionnaires from their patients. Patients can be given a URL for accessing their electronic patient record (EPR) so that they can monitor their file, see the
questionnaires needing their attention and the evolution of their health. Patients can enter more accurate and recent data; they can modify basic data to match their current situation and can request analytics that is performed on their own health data. By use of mobile Internet devices, for example, patients can enter symptoms before entering the practice of a medical professional, ensuring shorter time spent on each patient. Benefits for the patient include among others reduction of time needed to explain symptoms to the physician, easy access to data, automatic alerts for medication or appointments.

Outcome measurement can thus be improved dramatically by implementing web-based questionnaires that are simply modules in the system that can be inputted rapidly by means of computers and digital devices. After the input is done, it can be either digitally or manually completed. In the case of the POMT, digital questionnaires are used. Delaware Consulting, the builder of the POMT, has built the POMT around questionnaires that aim to capture parameter measurement based on patient reported outcomes.
4 The Patient Outcome Measurement Tool (POMT)

Before we can explain what exactly the Patient Outcome Measurement Tool or POMT actually is and does, it is important to illustrate how the system came to be and how it can be situated within the gigantic corporation that is Johnson & Johnson. We will discuss briefly Johnson & Johnson, what they do and how they are structured. After that we will discuss the POMT and how it came to be. After that, we will talk about what the intentions are and the future perspective is of the system. Finally we will make the transition to chapter 5, wherein we will discuss how the POMT provides an answer to the challenges we identified in chapter 2.

4.1 Johnson & Johnson company overview and structure

Johnson & Johnson is a holding company consisting of 3 main groups. It was founded in 1887. The activities of the company and its subsidiaries consist mainly of the research and development, manufacturing and sale of a broad portfolio of products in the health care domain. The company “has more than 250 operating companies conducting business worldwide”. The Johnson & Johnson Family of companies currently operates in 3 business segments:

- Consumer
- Pharmaceutical
- Medical Devices & Diagnostics

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The Johnson & Johnson Family of Companies operates in 60 countries and has a workforce of approximately 116000 people. The worldwide headquarters of the company is situated in New Brunswick, New Jersey, USA\textsuperscript{50}.

As mentioned above, Johnson & Johnson’s activities can be largely categorized into 3 separate businesses segments. As we mentioned before in our discussion, the Patient Outcome Measurement Tool can be seen as an initiative coming from the division of Medical Devices & Diagnostics, specializing in the development and manufacturing of medical devices such as stents, prosthesis and diagnostics equipment such as scanners and glucose meters.

### 4.2 Medical Devices & Diagnostics

The Johnson & Johnson Family of Companies comprises the world’s largest medical devices and Diagnostics Company\textsuperscript{51}. The Medical Devices & Diagnostics segment includes a range of products distributed to wholesalers, hospitals and retailers. Physicians, nurses, therapists, hospitals, diagnostic laboratories and clinics principally use them in their respective professional fields. Distribution to these health care professional markets is done both directly and through surgical supply and other dealers\textsuperscript{52}.


The Medical Devices & Diagnostics segment is comprised of several subsidiary companies each related to a specific health care market. Together they make up the Medical Devices and Diagnostics division of the Johnson & Johnson Family of Companies. A short overview of each of them and of their core results follows below.

- **Advanced Sterilization Products**
  Advanced Sterilization Products specializes in infection prevention and markets a full range of sterilization, disinfection and hand hygiene products that attempt to address the needs of health care providers and patients worldwide.

- **Animas Corporation**
  Animas Corporation’s activities are focused on diabetes management aiming to reduce long-term morbidity of the disease and to lower health care costs\(^5\).

- **Cordis Corporation**
  Cordis Corp. develops and manufactures interventional vascular technology. They are one of the world’s leading manufacturers of cardiac angiography catheters and a growing player in the larger cardiac angioplasty market. Throughout their history, they have been plagued by product recalls and marketing missteps. Cordis Corp. appeared to have found a profitable niche in the cardiac catheter industry in the early 1990s. Their sales more than doubled during the first half of the decade, from $202.6 million in 1990 to more than $443 million in 1995. Net income increased from $20.1 million to $50.2 million. Johnson & Johnson made a hostile bid to acquire Cordis Corp. in late 1995. They won the takeover battle early in 1996 with a $109

per share stock swap. Cordis Corp. was then valued at $1.8 billion because of this deal\textsuperscript{54}.

- **DePuy, Inc.**

  DePuy, Inc. is part of the Johnson & Johnson Family of Companies since 1998. This subsidiary of the Johnson & Johnson Family of Companies designs, manufactures, and distributes orthopedic devices and supplies. The company traces its roots back to 1895, which makes it the world’s oldest orthopedic company. DePuy, Inc. consists of 5 major divisions: DePuy Orthopedics, DePuy ACE, DePuy AcroMed, DePuy CMW and DePuy International.

  DePuy Orthopedics produces “hip and extremity implants, knee implants, environmental protection products, and surgical equipment”\textsuperscript{55}. Accounting for about half the total revenue of the company, this division forms the company’s core. Responsible for this success are the company’s joint replacement products, such as its pioneering AML Total Hip System and LCS Total Knee System.

  DePuy ACE produces specialty orthopedic trauma products. DePuy AcroMed then produces spinal implants and instruments. DePuy CMW produces bone cement. DePuy International, the company’s global arm,


has grown enormously as the company is actively expanding its overseas sales\textsuperscript{56}.

- **Ethicon, Inc.**
  Ethicon, Inc. is specialized in surgical sutures (stitches) for more than 100 years. The company has expertise in the sectors of wound management, women’s health, urology, bio-surgery, general surgery and aesthetic medicine. It is comprised of 4 business units that operate separately under the Ethicon brand name.

- **Ethicon Endo-Surgery, Inc.**
  Ethicon Endo-Surgery, Inc. develops and markets advanced medical devices for minimally invasive and open surgical procedures. It focuses on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, gynecology and surgical oncology.

- **Johnson & Johnson Vision Care, Inc.**
  Johnson & Johnson Vision Care, Inc. manufactures disposable contact lenses in order to address visionary limitations of patients.

- **LifeScan, Inc.**
  LifeScan, Inc. specializes in blood glucose monitoring systems for home and hospital use. Its product line in this segment is called One Touch®.

- **Ortho-Clinical Diagnostics, Inc.**
  Ortho-Clinical Diagnostics, Inc. is a provider of high-value diagnostic solutions for the global health care community. This subsidiary of Johnson & Johnson specializes in developing tests for early detection or

\textsuperscript{56} Ibid.
diagnosis of disease. It aims to provide timely information in order to facilitate better medical decisions\(^5\).

- **Virco BVBA**

  Virco BVBA is a Belgium-based, research-based biotechnology company aiming to improve the diagnosis and management of infectious diseases by applying advanced technologies in molecular biology, virology, genomics, robotics and electronic data processing. Today they are primarily dedicated to combat HIV through the combined application of above-mentioned technologies.

  Johnson & Johnson acquired Virco BVBA in 2002\(^5\).

As we can see from this brief overview of the Medical Devices & Diagnostics branch, Johnson & Johnson is a sizeable holding company representing much of the products used daily in hospitals and doctor’s offices around the world. Besides the MD&D division, Johnson & Johnson is market leader in the production of generic medicines through its acquisition of Janssen Pharmaceutica and its incorporation in the Johnson & Johnson family of companies.

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4.3 The Patient Outcome Measurement Tool (POMT)

4.3.1 Financial background

The Patient Outcome Measurement Tool is an initiative of Johnson & Johnson’s Medical Devices & Diagnostics (MD&D) branch. More specifically it is a joint effort of Ethicon, Inc. and DePuy, Inc. It has evolved from an initial investment of 15000 Belgian Francs, converted around 370 EUR (Currency conversion: 1 EUR = 40.3399 BEF\(^59\)), to an investment estimated around 2 million Euros, which is the total investment accumulated over the lifetime of the project. Although the POMT was a joint investment of two of the biggest subsidiaries of Johnson & Johnson MD&D, DePuy, Inc. and Ethicon, Inc., the juridical responsibility of the investment is located with the country manager of the MD&D division.

Because of discretionary reasons, and because this is not the topic of our discussion, we will not further elaborate on the financial background of the POMT system. Johnson & Johnson placed the POMT within their strategy roadmap for MD&D division and finances it completely with private funds. This implies that the government at the moment is not contributing anything through subsidies or fiscal benefits, leaving the POMT system out of sight for deeper financial analysis. What we do want to focus on, is the positive effect of opening up the POMT to the medical research community as well as to medical practitioners.

4.3.2 What is POMT?

As discussed earlier, the MD&D branch of Johnson & Johnson produces, among others, surgical products, prosthesis, treatment equipment and supporting devices for clinical research and medical imaging. The POMT project is related to

these activities through the strategic goals Johnson & Johnson wishes to achieve through the widespread use of the POMT.

Johnson & Johnson defines the Patient Outcome Measurement Tool or POMT as:

“A value added service from Johnson & Johnson Medical Devices and Diagnostics towards individual clients and/or research groups”60.

The part of the POMT that is aimed at the clients, the payers in this case, can be defined as:

“A web based data collection system, where (inter-) nationwide data registry is done by health care providers, their respective teams and patients in the context of research, quality assurance (patient safety) and health economics”61.

The POMT project supports evidence generation through data collection in a simple way and with proven technologies. A key aspect of the system is the inclusion of the patient in the data gathering process. This approach holds a regular capturing of patient data through Quality of Life (QOL) questionnaires at regular intervals. Benefits of this approach can found in increased ownership of the data and the treatment as a whole as well as a lowered burden for data collection for the surgeons and other medical professionals62.

For the individual hospital the POMT can serve a few goals and needs. First, from a scientific approach, the POMT is a user-friendly data-gathering tool with swift access to analysis tools with functionalities to export data to common formats such as Microsoft Excel. Second, it can serve as a tool for multi-disciplinary and trans-mural patient care. Third, the data it holds and the outputs it can produce

61 Ibid.
62 Ibid.
can be used in negotiations with the payer concerning patient safety and cost-effectiveness of treatments and products\textsuperscript{63}.

On an international level, the level of the scientific workgroup, the POMT aims to reinforce Best Practices and guidelines. By offering a tool to register all data and being able to share data across hospitals and thus across medical professionals, best practices and guidelines can be streamlined and generalized. This will reduce redundancy, communication errors and improve transparency across the board. Medical mistakes will become more apparent and root cause analysis can be performed with the help of the outcome data so that mistakes can be avoided in the future.

Johnson & Johnson considers the POMT as a readily available platform to support clinical trials. It is configured by Johnson & Johnson, independent of an Information Technology (IT) Supplier/Vendor. Not being dependent on an IT vendor results in a reduced time-to-market of the products and allows a flexible system that can respond rapidly to changing markets while still maintaining full control over the roadmap of the system and how it should be implemented.

Looking at the credo of Johnson & Johnson\textsuperscript{64}, it shows that Johnson & Johnson as a company aims to put the patient central in their activities. Today there is too little control on the results physicians and surgeons achieve and the information that comes out of clinical procedures. Information is spread over innumerable sources, individuals and institutions. This has dramatic effects of patients not being treated in the most efficient and effective way, resulting both in a loss for the patient in sense of quality of life and for the payer as the treatments performed or products used cannot be proven to be the ones with the optimal cost-benefit ratio. Clearly it is important to be able to establish best practices

\textsuperscript{63} Ibid.

and golden standards for treatments, products, medicines and care paths. Knowledge sharing, responsibility, accountability, efficiency and effectiveness are the key concepts in this discussion.

### 4.4 Efficient Treatments, Treatment Parameters and Golden Standards

A medical treatment can be called efficient when they achieve at least as good a result as the golden standard prescribes, preferably at a reduced cost.

Medical professionals grouped together in workgroups write guidelines on treatments and diseases. These workgroups are assembled according to each medical field and within the field according to each disease. Experts, medical professionals deemed excellent professionals by their colleagues in their respective fields, lead these workgroups of medical professionals. The goal of such a workgroup is to define guidelines for certain treatments or care paths. These guidelines describe what ‘good medicine’ should be like and to which standards a certain treatment must adhere. Each of these guidelines is rewritten and adapted to current trends and evolutions in their fields. These adaptations and controls are performed every few years.

Together the workgroups work out and map golden standards for medical procedures. Each procedure or treatment can then be tested according to these golden standards. Each physician in their field accumulates the golden standards into a database. The research conducted by these workgroups is attained through intensive literature study and through the usage of methodologies such as the Cochrane Reviews, a systematic review of primary research in human health care and health policy, and internationally recognized as the highest standard in evidence-based health care.

So how is the quality of treatment assessed? Throughout a treatment or procedure there are certain parameters that are registered to assess the quality
in general. These parameters are bundled in 4 broad groups of individual parameters, with the last group, economic impact, being the most recent and least described parameters.

1. **Patient satisfaction or Quality of Life (QOL) parameters**
   As one of the most important parameter groups, the quality of life indications register the perceived comfort and perception of quality of life through the eye of the patient. Often labeled as the most important parameters, the quality of life group of parameters is measured through the use of standard questionnaires. One such questionnaire is the standard SS36 questionnaire. In this questionnaire an initial measurement of the parameters is done before the treatment is started or the procedure performed. After the treatment or procedure is executed, another measurement is done with the same questionnaire to assess the changes in the responses, hoping for an improvement in all parameters.

Examples of such questions on QOL parameters include:

- How are you feeling?
- Can you walk without problems?
- Can you walk up the stairs without problems?
- Is it possible to take part in sport activities?
- Can you consume a meal without problems?
- Do you have normal appetite?

2. **Clinical parameters**
   When a patient comes to a medical professional with a disease image, certain parameters need to be assessed so that the correct disease image can be determined. The patient will have to answer questions concerning the symptoms they are experiencing and the earlier history they may have concerning diseases and treatments.
Examples of such questions on clinical evaluation include:

- Which symptoms are you experiencing?
- Do you feel tired?
- Do you feel a strong pain in your stomach?
- Is there swelling in the area where you experience pain?
- Do you have problems swallowing food?

Each of these questions is meant to determine which disease image applies to the symptoms the patient is reporting. It is a purely clinical assessment of the situation and does not yet involve technical parameters, which are the next group of parameters relevant in assessing treatments.

3. Technical parameters

Technical parameters are those parameters that apply to the technical aspects of a treatment or procedure. They are based purely on technical assessment of a disease, its treatment and its outcomes. They involve the application of a procedure, of a product, therapy or of medication. These parameters can’t be taken into consideration without the other 2 groups of parameters.

Examples of technical parameters include:

- A patient suffers from cholesterol levels that are too elevated. This is determined through a blood sample test. A medicine for reducing cholesterol levels in the blood is prescribed. After 2 weeks blood samples are taken again to assess cholesterol levels in order to determine the correct working of the medication.

- A stent is placed in the artery of a patient who suffered from a heart attack. After some weeks the cardiologist controls if the artery remains open thanks to the stent.
4. Economic impact

A new group of parameters has risen in recent years in response to tightening budgets and the need for financial discipline in domains of social security, especially in the health care domain. The payer has spent more and more on refunds because medical professionals determined if a treatment made sense for a patient or not. Governments are claiming that the medical professional can no longer be the sole stakeholder to make a decision. The payers have to be involved together with the clinician and the industry.

Through the usage of golden standards, treatments and products, that are introduced as new, must be of the same or better quality than previously known treatments and products, preferably at a lower cost. The cost-benefit relationship of a treatment is no longer a parameter that can be neglected; it is what helps the payer make the final decision in which treatments are eligible for refund and which aren’t.

Examples of economic impact parameters include:

- Is the cost of the treatment higher than average treatment cost?
- Is the optimum cost-benefit achieved?
- What is the expected success rate for this treatment?
- Could the treatment have been performed with a cheaper product at same quality levels?
- What is the Return on Investment of the performed procedure?
- Is the risk of further complications reduced?

Literature study has mostly given attention to the parameter groups of clinical and technical parameters. These groups of parameters are the easiest to measure and also of great importance to uphold procedural discipline. They do not however take into account the human and economic aspects of treatments or
used products. The POMT tries to capture especially the QOL and economical parameters in order to optimize care paths, treatment and products used for treatments. By registering these parameters, next to the familiar clinical and technical group of parameters, care can be optimized in a whole new way allowing financial discipline and more transparency in budget control for health care. The payer will refuse treatments deemed inefficient or not cost-effective. Of course the patient then still remains the option to perform procedures, though be it at his or her own cost.

When assessing the quality of the delivered work by a medical professional we can make a distinction between the competence levels of medical professionals. A degree from an educational institution alone is not a guarantee for having quality in the performance of a medical professional. In order to optimize the quality of the performed treatments to the patient, Johnson & Johnson offers education and support to medical professionals. By doing this, Johnson & Johnson hopes to position the POMT project in this vision of achieving better results for the patient and optimizing their quality of life through better care and more agile responses to the market.

Johnson & Johnson offers POMT to the entire medical and clinical research community. Should Johnson & Johnson offer the POMT exclusively to their clients, this would create bias and thus endanger the targeted goal of creating the reputation of a respectable partner in clinical research. The POMT produces the best analytical outcomes when more data is processed from verified and trustable sources. The larger the data sets becomes, the better the data can be generalized and used for medical research, improving quality in general. Because the POMT is only accessible by registered medical professionals, we can assume that the quality of the data going into the system is high. However, caution should at all times be established, as practitioners can tend to make certain mistakes, be it willingly or unwillingly. The medical professionals themselves benefit directly from ensuring correct and timely data being entered in the POMT,
as they will obtain more valuable information in order to improve their own procedures.

However it could be useful to consider putting in place financial incentive programs, such as those used in by NICE in the United Kingdom\textsuperscript{65}. In that framework, medical practitioners are rewarded for how well they care for their patients. That means that the outcomes of their patients are analyzed and processed to determine which practitioner cares best for their patients. Although this may seem as a good incentive to reward medical practitioners, we need to caution for some of the parameters that influence the outcomes.

1. **Geographical location**
   When the practitioner is located in densely populated areas, the risk of inflictsions and harm are higher than in those areas that are less densely populated.

2. **Externalities outside of control**
   Some practitioners may be situated in areas where there is chronic pollution in the environment. This will lead to worse outcomes for those practitioners in the area and thus would affect their financial rewards negatively.

3. **Falsification or misrepresentation of results**
   We have to question what security measures are taken for dealing with the accuracy and reliability of the outcomes that are inputted into the system. How is the outcome data verified and how relevant is it?

As we illustrate, there are concerns surrounding the financial and economic incentives for medical professionals. If we put in place these kinds of systems, we must guard over the quality and reliability of the data it produces.

4.5 Delaware Consulting: Builders of the POMT

Delaware Consulting is responsible for building and maintaining the POMT from a technical point of view as Information Technology (IT) vendor. Delaware Consulting is a Belgium-based IT vendor specializing in business solutions based on proven platforms of SAP and Microsoft. Delaware Consulting believes in the GLocal approach, which consists of Local entrepreneurship and a Global vision and collaboration. Delaware Consulting operates in 7 countries with branches in Belgium, China, France, Luxembourg, The Netherlands, Singapore and the United States of America. The global headquarters is located in Kortrijk, Belgium. Within Belgium there are 2 more branches, one in Berchem, Antwerp and one in Wavre, Waals-Brabant. The complete Delaware group accounts for 600 employees around the world\textsuperscript{66}.

According to Johnson & Johnson, they have chosen Delaware Consulting for their proposed technologies and the flexibility they showed when it comes to adaptability of the POMT. The chosen technologies were especially important since the idea of questionnaires as the heart of the system brought with it a problem in scalability of those questionnaires. Delaware Consulting introduced new and innovative technologies such as Adobe Flex, which anticipated on the scale the POMT would hold and the expansion across borders and continents.

4.6 Questionnaires

Questionnaires are the heart of the POMT. Because of the approach Delaware Consulting used, there is much control for Johnson & Johnson to create, adapt and analyze the questionnaires in the system. It comes down to Johnson & Johnson being able to produce, compose and analyze the questionnaires in the POMT without need for an intervention of the IT vendor to code the questionnaires or manipulate the database to deliver the results. This allows Johnson & Johnson to respond quickly to questions of clients and shortens the time needed to gather data on products, diseases and treatments.

In the case Delaware Consulting would design and implement each questionnaire, both Johnson & Johnson and Delaware Consulting would encounter significant costs. Delaware’s staff would have to be trained to learn about medical terminology and concepts as well as the processes of patient treatment procedures and surgical operations. Johnson & Johnson, on their side, would have to free up staff and resources to deliver training to developers and analysts, creating significant overhead costs and requiring larger budgets for the POMT project. Delaware Consulting and Johnson & Johnson together solved this significant issue by constructing a configurator that allows Johnson & Johnson medical staff to design and implement the necessary questionnaires for each medical field. Training and education thus only requires Delaware staff training Johnson & Johnson staff one time to teach Johnson & Johnson staff to operate the configurator.

A questionnaire instinctively can be defined as a composed set of questions, strategically formulated with the intent of collecting relevant data from the participants involved. In market research a questionnaire can be both intended for self-completion by survey participants and as a survey that should be administered by an interviewer. This interview can either happen in person, face-to-face, or it can be conducted by telephone {Brace:2008ut}. New ways of conducting surveys is through web-based systems or native applications for
computing platforms. The participants can then complete a questionnaire in the comfort of their own home, or any other location they happen to be at, by logging into the system from their own computer or mobile device. Within the context of questionnaires, where questions are organized in fixed lists and paths, there are only a few downsides in using this new method of administering questionnaires. Downsides include among others varying reliability of Internet connection and varying skill level in computer usage among participants.

The POMT is set up in a way that the patient receives a login to the platform. In the POMT the patient can consult his or her patient record and consult which questionnaires he or she is expected to complete. Medical professionals can assign questionnaires to patients and then consult the results that are also taken into the data set that can be extracted

4.7 Costs and motivation for building the Patient Outcome Measurement Tool (POMT)

Building the POMT was a considerable investment for Johnson & Johnson but as it is with financing projects, Johnson & Johnson hopes that the benefits in the long run will outweigh the costs, directly and indirectly. Direct benefits include license fees, image building, brand positioning, product development and marketing. Indirect benefits can be the credibility of the company as a trusted research partner, new product ideas and concepts. Because Johnson & Johnson is a company with profit motives, it can be a challenge for them to position themselves as a reliable and trusted research provider that can eliminate bias and competitive behavior in performing research. It is important therefore that Johnson & Johnson does not have access to the data flowing into the POMT. When we look at the architecture of the system it’s clear that this is indeed provided in the POMT. POMT does give Johnson & Johnson a benefit over its

67 Delaware consulting. Unpublished manual for the POMT.
competitors in the form of closer cooperation with medical professionals, which in turn can lead to improved product development and more close idea generation benefiting Johnson & Johnson. It is important then to monitor and control the safety of patient data so that privacy issues are avoided.

The costs for developing, positioning and maintaining the POMT are composed as such:

1. **Development costs**  
   Development costs for the POMT project include the costs incurred by having the system built by an IT vendor. In the case of the POMT, the contract was granted to Delaware Consulting with worldwide headquarters in Kortijk, Antwerp. Development included analysis, building of the system and implementation in the first health care domains.

2. **Maintenance costs**  
   Maintenance costs for the POMT project include the costs for additions and changes to the system as well as keeping the system compatible when updates occur to operating systems or browsers. Also the compensation for 3 employees within Johnson & Johnson is included in these costs. These 3 individuals represent 2 fulltime equivalent employees and are billable based on the training and education they deliver to the users of the POMT.

3. **Ad hoc costs (Overhead costs)**  
   Among these costs are costs incurred for travel expenses of staff, training seminars, conference costs, presentation costs. The compensation of the project lead is part of this category of costs as well.

From the above analysis we can indicate that the POMT project was a significant initial investment for Johnson & Johnson and continues to be an investment carried on over the lifespan of the project.
Strategic goals

Johnson & Johnson aims to achieve a number of strategic goals by offering the POMT to the medical community. First we define some concepts relevant to this discussion.

- **Payer**
  The payer is defined as any institution; body or organization that commits itself to carrying the partial or complete financial burden accumulated through performed procedures and used products for their client, the patient. Included in this category are Health Care Insurance Companies, the government and mutuality funds.

  In Belgium, the Ministry of Health is involved as a health care insurer through RIZIV (‘Rijksinstituut voor ziekte- en invaliditeitsverzekering’ translated as ‘Realm Institute for illness- and invalidity insurance’) and the mutuality funds, who ensure the refunds of medical costs to patients.

- **Mutuality funds**
  Mutuality funds in Belgium are government-controlled institutions that process the administrational burden of medical interventions. They are empowered to distribute refunds of medical interventions and products to the client, the patient. Each patient in Belgium is by law obligated to be a member to one of the mutuality funds in order to recover his or her medical costs from the government’s social security system.

As we stated above, Johnson & Johnson aims to achieve a number of goals and benefits for themselves and their clients.

The payer of health care wishes to obtain transparency and cost-benefit analysis of chosen procedures and products. Treatments, products and procedures must
make financial sense and must be efficient for the payer so that there can be sufficient control over the budgets and expenditures. In recent years, the health care costs in many welfare states have risen rapidly and have now taken dangerous proportions for the continuity of social security systems. These increases in costs have to be followed by an increase in budgets for health care in these states. Given the recent economic and financial evolutions in the worlds’ most important economies, especially the aftermath of the financial crisis of 2008, the increase in budgets is no longer sustainable. Governments and other payers are looking to the medical industry to supply means of controlling and monitoring care and treatment paths so as to optimize them in a financial sense without sacrificing quality, even improving quality if possible. Each euro that is spent on medical care is now under intense scrutiny from the payers. Cost effectiveness has become a primordial condition for being eligible for a refund of performed medical services.

Clinical studies have been a first step in achieving this transparency. They do however suffer from a limitation that they have to take place in an intensely tight and directed setting. A limited number of centers with highly qualified specialists with a very tightly selected patient group are monitored under strict protocols. Obviously this doesn’t represent the daily health care that a payer is willing to finance under a normal setting. Therefore the payer wishes that all medical professionals are able to collect their data and to present it for potential audits should the payer wishes to perform these audits.

Concerning the medical industry, the payer demands that they as well can present such analytical data concerning new devices, medicines or treatments when they are about to introduce a new product to the market. In the past, all the medical industry had to do to be able to market a product was to convince the doctors of the clinical benefit of their products. Doctors then approved of the products on their own, without government regulation monitoring these procedures. Subsequently products were marketed and medical suppliers were
forced to attract doctors to their products by giving the best conditions compared to competitors.

Now however, the payer has to be convinced of the economic benefit of the products. Doctors still have an important role to play in assessing clinical importance and quality of the products but the payers are now the ones deciding whether or not products are eligible to be marketed and used in clinical settings.

We turn then to the discussion of the POMT as a project. Johnson & Johnson has noticed earlier on that although the need is high for a system like the POMT. Individual medical professionals don’t have the time, resources or the process discipline to implement a project such as the POMT. The medical industry has competencies, an arm reaching all over the world and vast financial, infrastructural and people resources to be able to finance, maintain and rollout such a project on a global scale.

So we then can ask why Johnson & Johnson is willing to finance all of this. First of all, without accurate and relevant data there is no refund by the payer. This inclines that when there is no data, surgeons and doctors won’t be willing to perform certain treatments or use certain products, as the costs would rise too strongly for them.

Social welfare systems are built on the fact that the payer carries the majority of the financial burden of medical interventions. A logical consequence of this issue is that the sales of Johnson & Johnson’s products would be non-existent. Johnson & Johnson wishes to facilitate its own market by offering the POMT to the medical community. By doing this, Johnson & Johnson takes away an important barrier that would otherwise prevent the payer from approving treatment and product decisions. Johnson & Johnson thus directly benefits by being able to sell more products to their clients and by doing this increasing their revenues. Financial and marketing motives are clearly present. Is this then a bad thing we can ask ourselves? As long as Johnson & Johnson doesn’t obtain patient data for
financial gain, privacy issues are non-existent and therefore the major concern of privacy issues is eliminated. However, how can we ensure that the data will at all times be protected? A logical suggestion would be to install a supervisory (regulatory) body that can make decisions on the balance between private interest and the common good, as well as make sure data is at all times protected and safeguarded by a neutral body.

Second, Johnson & Johnson is in possession of clinical studies performed by medical professionals. The problem with these studies however is that they are relatively small in size and are often linked to one specific country, often the United States of America, home to Johnson & Johnson’s global headquarters. By collecting outcome data, not patient data, through the POMT, Johnson & Johnson is able to obtain local data that can enhance their market access activities significantly. Again the issue of privacy and data protection is a relevant one in this context.

Finally, the POMT system positions Johnson & Johnson as a respectable partner for physicians and surgeons in supporting them in their medical research activities. Johnson & Johnson aims to be a respected partner for research initiatives with as this creates a sentiment of trust and reliability between them and the medical community, giving Johnson & Johnson competitive advantage in obtaining clinical research for their products. This then creates the benefit of shorter time-to-market timeframes.

4.8 Health care domains served by POMT

The POMT serves only a few medical sectors for the time being, since the system is not yet fully rolled out. The medical sectors that are given access to the POMT are carefully chosen based on the needs they exhibit. The most urgent sectors in sense of needs received priority in implementing the POMT. Required for implementation is only a normal personal computer with an broadband internet connection.
For the time being sectors where POMT is being used include gynecology, bariatric surgery and chronic sinusitis. The intention is to roll out to the complete medical domain.

4.9 Geographical expansion and strategy

Johnson & Johnson is a global company operating in more than 60 countries. The POMT was initially projected for rollout in the Benelux. Since the POMT does not require extensive investments in infrastructure or contractual fees, the spread to other regions of the world was only a matter of time. This means that the POMT can be distributed to any country of which the infrastructure, culture, legislation, politics and health care system allows for the deployment and use of such a system. Deploying the system itself is a minimal fraction of the development effort and cost. In essence, deploying the POMT in a new country is a matter of copying the system and making modifications in sense of language, legal obligations and other localization procedures. Since it is completely a web-based platform, requiring only a browser and internet connection to access it, the rollout can be fast and without many technical pitfalls as the technology is standardized and proven.

Expansion does bring challenges for Johnson & Johnson MD&D. These challenges first lie mostly in the direction of legal issues and obligations, privacy issues, because of specific legislation, and cultural barriers.

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4.10 Competition for POMT

One might ask the question whether it is possible for a system such as the POMT to have significant competitors, let alone competition at all. As we stated before, Johnson & Johnson utilizes the POMT not only for helping advance the medical community, private interests for the company also play a role. The balance that needs to be found lies somewhere in the zone where private interests meet with interests of the general public so that they can complement each other, benefiting each other in a win-win situation.

When we consider competition, we can state that other pharmaceutical companies clearly would have an interest in owning a system such as the POMT. Because of its market penetration benefits and the beneficial effects on the image of the company as a research partner, competing medical companies are interested in obtaining a similar system.

Competition in this market will not always yield good results. If it so happens that many registries exist, data can become redundant, data will be fragmented and competing interests will drive down the quality of the data. Competition in this market is not something to stimulate, as medical registries should not be the topic of competition for market share.

The government will need to consider possible action to regulate and control medical databases and registries.

4.10.1 PROMIS

A competing system that is already on the market in the United States of America (USA) is PROMIS or Patient Reported Outcome Measurement Information System. “The main objective of PROMIS is to be a system of highly reliable, precise measures of patient-reported health status for physical, mental,
and social well-being. Similar to the methods of POMT, PROMIS uses a questionnaire to determine patient’s abilities, how the patient feels, both physically and mentally, and what the evolution is in the patient's state. PROMIS’ idea arose out of clinical research issues. Researchers had found that the need for more valid, reliable, and generalizable measures of clinical outcomes that are important to parents was growing because the conventional measures of treatments and the evolution of the patient did not fully grasp the way diseases and their treatments affect patients.

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70 Ibid.
5 POMT and the challenges in health care

The Patient Outcome Measurement Tool was created with both strategies for Johnson & Johnson in mind but also to anticipate to the coming challenges the health care sector faces. Outcome measurement is one of the many aspects of health care that will contribute to a more cost-effective health care delivery. Medical registries such as the POMT pave the way for technology to become the driving force of change in a domain as complex as health care. We have seen in the previous chapters that,

1. Health care influences and touches every person’s life.
2. Health care is expected to be accessible, qualitative and give freedom of choice.
3. Health care is one of the most expensive social programs in any society in the world.
4. The challenges facing health care are enormous.
5. Information technology can drive the necessary change and bring more qualitative, accessible, flexible and more efficient health care to patients.

We will now discuss the challenges for the health care sector that we have identified in chapter 2 and discuss how the POMT might play a role in helping to solve the challenges health care faces.

5.1 Challenges in social organization of the health care sector

As we stated in chapter 2, the health care sector is undergoing a very turbulent time with budgets being under increasing scrutiny and patients demanding accessible, qualitative health care in which they can have some freedom of choice. So how can a system be modified to reflect these aspects?
We can’t identify one sole way to provide the above stated qualities in the health care system. However, the POMT can play a role in helping obtaining increasing quality and accessibility. The POMT gathers outcome data and provides this data for clinical research, after the appropriate approvals have been given. By providing a system to collect data in a structured and transparent way, the POMT can go a long way in helping medical professionals and financiers of the health care system to obtain more relevant and qualitative data. Based on this data they would be able to make better-informed decisions that should boost efficiency and effectiveness of care delivery.

Quality is one thing; making health care more accessible is something else. The provision of social services, of which health care is a big part of in most developed economies, is tightly related to the current political climate in said society. As we can see the health care system in the USA is restricted for some societal classes. In countries like Belgium, which also has significant private funding although be it differently organized, health care is available for everyone as everyone also is obligated to contribute. Accessibility is thus more of a sociological and political parameter that has to be the result of shifting mindsets. We are seeing that the provision of health care in the USA is one of the main campaign themes in the presidential election of 2012\(^\text{71}\). The outcome of this election will prove to be a paradigm shifts one way of the other.

We can thus conclude that the POMT will give way to more qualitative health care, given the correct usage and discipline mechanisms are in place. Results will be easier to compare, medical mistakes can be avoided, products and treatments can be optimized faster and more efficiently. Accessibility and freedom of choice are byproducts of the political and societal organization of the society itself; the POMT cannot exercise a direct influence on these two parameters.

5.2 Challenges in costs and financing of health care systems

The largest challenge awaiting health care systems and thus financiers of the system is the issue of rising costs on health care. As we stated in chapter 2, costs are rising faster than GDP growth. Health care inflation is outpacing inflation of consumer price indices. Controlling this trend will prove to be one of the main challenges of public and private financiers of health care around the world.

The POMT aims to help control costs by offering means to collect data, search for golden standards and best practices for medical professionals. When this process is optimized and defined accurately, medical professionals and stakeholders of the health care system will have access to more and more qualitative data. Based on this data, medical researchers can search for general trends, identify best practices and avoid medical errors through the knowledge sharing aspect of the POMT.

By using technology in health care, communication can improve, accountability will be enforced and sharing should become one of the main drivers among medical staff and payers. Online by sharing and working distributive, can these enormous challenges be overcome. In the end the POMT is only a tool providing a way to tackle some of the cost-related challenges. What we truly need in the health care context is a mentality shift from protecting one’s reputation and career to sharing and opening up the books so that we can install and facilitate continuous learning and improvement. Medical registries such as the POMT facilitate this behavior but in the end the people need to carry on the change and take the most out of the tools provided to them.

Since medical care is becoming more individual-driven, and this is shifting costs of treatments and development of products upwards, the POMT could prove to be a useful tool in optimizing these developments. By tracking the used products and treatments, registering the outcomes both from a procedural point of view and from the view of the patient, a useful data set can be gathered on the
condition that the data inputted is valid and verified. With this data, treatments and products can then be improved and optimized so that the costs incurred go down again.

5.3 Demographical challenges

5.3.1 Ageing of the population in developed economies

We stated in chapter 2 that one of the problems health care systems are facing is an increasingly ageing population and a demographic structure that is turned upside down. More people are going in retirement than there are babies born. This will prove to be one of the biggest challenges to overcome for the future generation on the condition that this trend keeps being as it is.

After all, how do we pay for social provisions for a layer of the population that outgrows the working class in size? Social services such as health care can only be provided to the people as long as there are enough people belonging to the active working population.

The POMT can again play the role of facilitating making the right decisions by people active in the field. By having access to correct data, clinical professionals can make more accurate and precise decisions on products, treatments and procedures. This in the end will help bringing the costs down in order to compensate for an ageing population.

Other alternatives such as working migration of highly skilled and educated people, as is proposed in countries such as Belgium, will be necessary in order to

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make sure the active population is large enough to sustain the non-active population in society.

How can the POMT then help in containing the 3 main challenges related to an ageing population? We will briefly discuss this topic below. As we stated in chapter 2, we can identify 3 domains that will drive increasing costs. However we can state that the POMT can’t make a direct contribution to the rise in demand for social care. This tends to be more the subject of societal debate and organization.

1. **Growth in chronic diseases**
   Because people are expected to live longer, they will also start to suffer from more chronic diseases. We have illustrated this in chapter 2. What POMT can mean in this context is again providing the tools to collect accurate information and outcomes on these diseases. Many chronic diseases are only now coming into the spotlight as an increasing number of people are suffering from them. The POMT can play a significant role in being a platform for collecting outcomes on treating these diseases. Based on this data, conclusions can be drawn and decisions can be made.

2. **Growth in multi-morbidity**
   The problem of multi-morbidity is still a recent one, as people never were expected to live as long as is now the case. In recent years, clinicians have been discovering relations between chronic diseases. Herein lies again the challenge of correctly diagnosing the diseases, understanding the relationships between diseases and formulating best practices and golden standards for improving quality of life as well as bringing down costs. The POMT will provide the data and possible expose correlations between diseases that were previously unknown or unfamiliar.
5.3.2 Lifestyle diseases

Bad lifestyles such as smoking, overconsumption of alcohol and obesity are strong drivers of several chronic diseases. Not only ageing poses a threat for the budgetary calculations of a health care system. As we saw from the table in chapter 2, the rate of people suffering from obesity is dangerously high and still increasing. People are undergoing surgeries in the hope to adjust their bodily complexes. This leads to an increase in the number of procedures performed and products used.

It will be thus of vital importance to correctly track and monitor the outcomes related to these procedures so that the costs can be contained. Costs herein are not only direct costs; they can also be regarded as the cost of having people being non-active because of procedural complications, patients suffering from psychological issues because of procedures or medication. Many indirect costs can be related to procedures when performed on members of the active population.

Again the POMT can play a role in providing a platform for data collection, preliminary data analysis and report generation so that clinical research can be facilitated and optimized and best practices can be identified. Medical registries that are already in use, such as EuCLID® prove that the sampling of more clinical data and gathering of patient outcomes will help in improving overall treatment results, reduce medical errors and improve the quality of care. Problems can be identified, solutions created so that qualitative health care can be delivered\(^{73}\).

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5.4 Attachment to existing systems and complexity

Implementing a new technology or system is always a challenge in any industry. Acceptance has to be present for a system to succeed in its targeted goals. Especially in a sector such as health care, where the choices in technology are only made once the technology is proven and sound and where different stakeholders all have different interests, acceptance is hard to attain. The POMT offers ways of gathering data, to make better decisions, available to medical professionals. However it can prove to be a challenge to adopt a certain technology.

After all there are several major barriers to ICT adoption in health care. When we look at the situation in the USA, it is shown that there are significant legal issues such as licensing, liability, malpractice and confidentiality. Next to legal barriers there are the financial barriers such as reimbursement agreements74.

Health care stakeholders will only adopt new technology to create higher quality products or treatments when the sum of new production costs, adoption costs, implementation costs and transition costs are lower than the amount consumers of the technology are willing to pay75. Especially lower production costs are vital for technology to be adopted. Production costs here can be seen as the cost for producing and composing certain treatments and medical products.

It is important to point out in this context the existence of “Network effects”. We can define a network effect as the effect the usage of a certain product by others around an individual or institution has on the value that person or institution


75 Ibid.
perceives it by. Together with positive feedback, network effects drive down product differentiation.

We can illustrate this with an example of the rise of social media. Years ago there were many social websites for different target audiences. There was MySpace for music enthusiasts, Friendster for people looking to maintain friendships, Orkut from Google, which mainly attracted Brazilians. All these websites have suffered drastically from the rise of Facebook. The power of Facebook was the network effect. People were going to Facebook and discovering this new social media portal that allowed them to share information in ways they hadn’t experienced yet. The more people saw their friends going to Facebook, the more they themselves wanted to join because it got more valuable for them. Facebook made it a top priority to ensure access to the site at all times, because they knew that if the site would be down even for 1 minute, people would move away because of the network effect.

This example illustrates that it is crucial that the network effects are taken into consideration. Acceptance will follow because the system gets more relevant the more people join in.

Adoption of technology can be a very complicated matter for a number of reasons. We select the ones relevant for the POMT.

1. **New technology requires training**
   Because people are taken away from their jobs to spend time training for using a new technology, the costs in the short run will increase due to lost time on the working floor.

2. **Switching costs can be significant in the ICT market**
   If Johnson & Johnson would want to switch from ICT vendor, it will bring significant costs for the company. Also if medical professionals would want

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76 Ibid.
to move away from existing systems in favor of the POMT, switching costs could be used in a strategic way to make sure POMT gets implemented.

3. Technologies must be interoperable.
   Related to switching costs is the interoperability of the system. Information is stored, manipulated and processed according to the system the data resides in. Reaching agreements on common standards can go a long way in dealing with this concern. For Johnson & Johnson not making data interoperable could be beneficial as they would be able to retain more people in the system. On the other side, if they want to be taken seriously they will have to foresee sharing and distribution of data.

4. Vendor lock-in can occur
   If the system is built on new unproven technologies, the vendor lock-in risk may be large and unfavorable for adoption. Stakeholders in the health care sector will not want critical data to be stored in a system that is dependent on only one vendor with specific technologies.

   Johnson & Johnson anticipated this problem and chose to implement proven technologies such as SQL Server and Adobe Flex, both platforms for which there are a wide range of companies offering services based on these technologies.

   Key to overcoming these adoption issues is to agree upon common standards of data exchange and data handling. This could be one of the tasks a regulatory body and/or government should take upon them so that private interests can not take over the debate.

What makes the health care market unique is that there are 3 interlinked markets existing within the sector⁷⁷. These markets are Health care services, Health insurance and labor market. The link between these different markets

⁷⁷ Ibid.
makes it more complex to deal with the demand of patients and medical professionals. Preferences can be much more indirect and blunted than those which exist in other normal markets where consumers need to make a choice. The payers need to have a clear view of the long-term benefits of medical registries such as the POMT. Over the long term it is about being able to treat better for less or an equal amount of money and effort. This should always be the main idea behind a registry even though in the beginning there will be some adoption costs.

Another issue adding to the complexity of implementing a digital medical registry is the patient itself. Often it appears to be that those people benefiting the most from using a medical registry are those patients with chronic diseases. However it appears that these people are often the ones with the least experience in using technology, let alone realizing the value of it\textsuperscript{78}. Patients will expect to see a return of participating in a new system or expect guidance when they do not own either the infrastructure or the knowledge to participate. This will drive up costs again. However we can foresee a change in this problem, as the current generation who are in the retirement ages today are a generation that never had much interaction with technology. Generation X, the generation that is supposed to go in retirement in the next 10 years, is a generation much more familiar to technology than the previous generation. They will prove to have fewer issues with technology than did their parents’ generation. Generation Y then will even see less problems in this domain as they are the generation that grew up with technology.

It is thus important to stress the rise of common technical standards in the health care market for a couple of reasons\textsuperscript{79}.

\begin{enumerate}
\item Standards enhance compatibility
\item Standards reduce the risk of incompatibility
\end{enumerate}

\textsuperscript{78} Ibid.
\textsuperscript{79} Ibid.
3. Standards reduce switching costs.

We can even go so far to say that costs in general will be brought down as a consequence of the lower costs in ICT adoption and implementation.

The socially optimal point of standardization in the health care market is reliant on the heterogeneity of its users\textsuperscript{80}. If ICT users prove to be more heterogeneous, flexibility will play an increasing role in the design of these systems. After all ICT systems need to be adopted by the users, not by the developers. We already know that the heterogeneity of patients in the health care sector is greater than that of consumers in other markets\textsuperscript{81}. A trade-off between more and less standardization will thus arise. More standardization will have positive effects on the adoption of ICT while less standardization will have positive effects on the product differentiation.

When looking at the products in the market, we can recommend standardization as it serves the common good and makes sure that information is distributable, easy to share and the outcomes will be more numerous. Private interests however can attempt to create platform specific data sets that limit the ability to share the information with other platforms. It is thus important to limit the dominance of one particular stakeholder or a group of stakeholders\textsuperscript{82}. A regulatory body could prove to be necessary. Examples of regulatory bodies when talking about standardization are the Healthcare Information Technology Standards Panel (HITSP) and the Certification Commission for Health Information Technology (CCHIT) in the USA. Together with different patient advocacy groups especially for those with chronic diseases will lead to greater acceptance because of involvement\textsuperscript{83}. The government plays a key role in aligning the different interests and making choices for the common good. Government intervention is

\textsuperscript{80} Ibid.
\textsuperscript{81} Ibid.
\textsuperscript{82} Ibid.
\textsuperscript{83} Ibid.
not excluded in this context. As the research we have consulted also mentions, the benefits of implementing ICT in health care context justifies the up-front adoption costs incurred.

5.5 Focus on prevention instead of reactive treatment

Systems such as the POMT gather data and produce analysis reports based on both patient reported data and outcomes defined by medical professionals. By collecting this information and storing it in a safe and efficient way, clinical researchers are able to perform accurate data analysis. Based on this data they will be able to determine best practices, improve quality of care and quality of life while performing tasks at lower costs. A big challenge for the next years will be to shift the way we see health care. It needs to be more focused on prevention rather than curing.

The POMT can help shifting this way of viewing health care by being a tool to collect data and allow for sharing of data so that complications can be predicted better, so that procedures and products can be optimized and the patients spend more time outside of the hospital or medical center then in them. Prevention needs awareness and awareness needs to come not only from the health care sector itself. The government has the biggest role to play here as they will have to adjust the budget accordingly so that prevention can truly become a driver of lower costs in health care.

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84 Ibid.
85 Ibid.
6 Conclusions

After intensively reviewing the literature and conducting interviews with Dr. Sorgeloose, I am confident to make some recommendations for improvement and implementation of the POMT. Also we would like to briefly point out some cautionary messages that need to be taken into account when rolling out a medical registry such as the POMT.

Healthcare is a domain that is complex in several aspects. Stakeholders and the relationships among them drive the whole system and determine how it is financed, how people receive care, what the financial impact is, what the quality of the care is, who can access the system, and many more aspects. It is a sector that is financed by a mix of public funds as well as intense private funding. This can often lead to conflicting interests between stakeholders leading to bias and unfairness. All people in the world should have access to qualitative health care. How the system is financed will determine in the end what the quality of life of any given person will be and even whether the person will live or die at some moments in their life. Think of procedures needing to be performed.

The challenges facing health care as a system but also to their stakeholders are enormous. The current budgetary situation of much of the developed economies does no longer allow for waste, variability and inefficiencies. No longer is it possible to perform procedures that are not necessary. No longer can products be approved just because a handful of medical professionals agree to the product or treatment, even though incentives from the medical industry could cause bias and conflicts of interest. The payer demands insight into how much products and treatments cost and why they cost as much or as little as they do. The payer, be it the government, indirectly through subsidies or the provision of infrastructure, or the insurance companies directly, they want to know why things costs as what they cost and how golden standards can be established. Golden standards will drive efficiency and effectiveness, improve best practices, reduce medical errors and improve the overall quality of treatments.
The way to collect this information is by analyzing outcomes. Outcomes can come both from patients and from medical professionals. In the past it has been the case that patients were little involved in establishing these golden standards. Now however, with the rise of digital medical registries, it has become increasingly easy to subject patients to questionnaires without burdening them with time-consuming and intensive methods. Outcome measurement proves to also be a challenge. Not all outcomes are relevant and the quality at all times should be safeguarded. How to do this remains the topic of much discussion in the medical community. They take a long time to collect, look like probability statements, create extra costs to collect and requires a large sample size to be truly relevant. However it is important for the stakeholders to point out that even though in the beginning it takes some effort both in human capital as well as in financial means, the long-term benefits of outcome measurement are significant. Reduction of medical errors, sharing of knowledge, reductions in time consumption for patients, preventative care all are benefits coming from the accurate collection of outcome data through medical registries.

It could prove to be efficient to install incentives for medical professionals to share knowledge and report results on their procedures, mistakes and products used. By creating financial incentives, medical professionals will be stimulated to take better care of their patients. However cautions need to be established. These cautions could be fraudulent reporting of wrong or misused outcomes, overemphasizing result-driven healthcare instead of caring for the patient, ignoring geographic and demographical data. Finding the right balance to reward contributors, who contribute the “right” data, will be a challenge for the stakeholders in the health care sector.

The POMT is a medical registry aimed at collecting those outcomes so that they can be organized, sorted, manipulated and analyzed so that they can form a scientific basis for clinical decision-making. The POMT aims to unify the different stakeholders, especially patients, treating doctors and the payer so that the value stream towards the patient can be optimized in a cost-efficient manner.
Again, some cautions need to be established. The POMT is a private initiative funded by Johnson & Johnson. Being a private company with shareholders to please, they could seem to have conflicts of interests when they would have access to data. Also we can question whether or not it is favorable for a private company to hold on to a system used by clinical researchers and directly affecting the way health care costs are reimbursed. Stimulating competition in this sector however will lead to increased fragmentation of data, loss of quality of data and loss of focus for establishing a qualitative system based on improving all aspects of the patient care. One solution for this would be to install a governing body, neutral and with enough authority to call to action the government and medical industry. They could safeguard the accurate collection of data, the quality of the data and protecting the privacy of the patients who participate in the system.

Thanks to medical registries filled with relevant outcome data, problems in procedures and products can be tracked rapidly which allows for rapid problem solving. This can affect the quality of life of many people directly. It will prove a challenge to roll out the POMT across countries and thus health care systems. Different countries deal with health care in a different way. However we need to point out that medical registries could potentially expose serious faults in some countries that have previously went undetected.

Also the adoption of the POMT will go hand in hand with technology adoption in the health care sector. This continuous to be a challenge and needs much attention. Adoption of health care ICT is dependent on the complexity of the health care market and needs to be thought about intensively before implementing a system like the POMT. The establishment of standards in data exchange and communication protocols is another task that could be contributed to a neutral governing body that is responsible for safeguarding the correct use of the system.
One of the most important warnings we have to point out is that health care ICT will never work unless it goes hand in hand with a shift in societal consciousness and different policies to correspond to changing conditions in both humanitarian aspects and financial aspects. Governments and society as a whole may need to rethink the way they see health care and what they expect from it. Focus will have lay on prevention of disease, stimulating healthy lifestyles and making sure people will become less dependent on health care. Procedures that are not necessary should be prevented from taking place and most of all citizens should be kept out of the hospital by ensuring they live healthy and take care of themselves. If there are no financial consequences to unhealthy lifestyles or risk-taking, it could prove to be very demanding to align people in the right direction. On the other side, if health care is too expensive, it could directly affect the quality of life of patients as they won’t be able to pay for health care or are being pushed into unhealthy lifestyles because of financial reasons.

We can thus conclude that medical registries such as the POMT will prove to be very useful in the future, on the condition that these cautionary messages are taken into account. The POMT is not a solution to all the problems in the health care sector but combined with the right policies and mind shifts, it will prove to become a driving force for improving the quality and accessibility of health care. In the end the goal should be a health care system that is accessible to all, qualitative and where freedom of choice has its rightful place.
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