Six Sigma in European Public Health Care: a proposed comparable model

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Chase the culture anywhere around the world.

Abstract

Six Sigma is commonly applied and well established in the manufacturing sector, especially in the USA. Since the beginning of the 1990s several public administrations, particularly in the field of health care, have also been implementing Six Sigma.

In Europe, public health care is very different from US health care in terms of organisation and its relationship with stakeholders. A specific Six Sigma model for European public health care is missing from the literature. In order to gain real advantages for such a health care system it is worth analysing, discussing and designing a possible dedicated model and comparing it with the manufacturing one.

The idea of such a comparison has originated from the Italian public health care system. In fact the Italian health care sector has a mission and values, a culture, an organisation, strategies and processes that are often very different from the production sector. However, many of these differences can also be found in European public health care. As described in the first chapter, among the European systems there are fundamental common features that can justify a dedicated research.

In order to achieve the aim, the thesis has been conducted in two stages. Although the thesis is primarily deductive, the first stage is typically inductive and the second one is deductive. A third minor stage based on qualitative–inductive methods helps to put the finishing touches to the proposed model by showing the differences from the manufacturing model and the features of the European system.

The final model attempts to make new contributions to the literature by primarily bringing knowledge to the stakeholders in the academic field and secondarily to the practitioners. The main contribution is surely a roadmap for shaping a missing Six Sigma model for European public health care.

Table of Contents

ACRONYMS

BB	Black Belt
BPR	Business Process Reengineering
COPQ	Cost Of Poor Quality
Cp, Cpk	Process Capability measures
CTQ	Critical To Quality characteristic
DFSS	Design For Six Sigma
DMAIC	Define-Measure-Analyse-Improve-Control
DOE	Design Of Experiments
DPMO	Defects Per Million Opportunity
EU	European Union
FMEA	Failure Mode and Effects Analysis
GB	Green Belt
IT	Information Technology
MBB	Master Black Belt
MSA	Measurement System Analysis
NHS	National Health Service
PDCA	Plan-Do-Check-Act
QFD	Quality Function Deployment
R&R	Repeatability and Reproducibility
SMED	Single Minute Exchange of Die
SPC	Statistical Process Control
SSH	Social Security Health care system
TPM	Total Productive Maintenance
TQC	Total Quality Control
TQM	Total Quality Management
VSM	Value Stream Mapping
WIP	Work In Process

Chapter 1 – Introduction: definition of the subject of the research

1.1 Introduction to the subject of the research

This PhD thesis aims to seek a specific Six Sigma model for the European public health care sector. Six Sigma originated in the 1990s in the USA and the term ‘Six Sigma’ was first used by a Motorola engineer. In a statistical way, Motorola correlated the standard deviation (the so-called sigma or σ) of a process around an expected target with the number of defects and the cost of poor quality to which the organisation is subjected.

Six Sigma uses tools that are largely derived from Total Quality Management (TQM) to reduce variation around the defined targets (Harry and Schroeder, 2000). The tools are used within a specific pattern called ‘Define, Measure, Analyse, Improve and Control’ (DMAIC). This rigorous pattern has to be strictly followed by improvement teams formed by Black and Green Belts (Antony and Banuelas, 2002). These latter are managers that receive a well-coded training based on statistical advanced tools. Chapters two and three will explain Six Sigma in detail and try to locate Six Sigma philosophically.

Six Sigma, as discussed in the third chapter, can be compared with other models such as Lean Thinking, TQM and Business Process Reengineering (BPR). Along with these it can be classified as a management system that leads towards business excellence (Carr and Littman, 1990; Ho and Fung, 1991; Kanji and Wallace, 2000; Klefsjo *et al.,* 2000) and improves business performance in general. In particular, Six Sigma is very focused on cost reduction through the avoidance of defects in the processes and products.

Since the 1990s many organisations, especially US organisations, have implemented Six Sigma and have achieved positive results in terms of savings, customer satisfaction and improvement of their processes. At the end of the second chapter it will be clear how Six Sigma is currently consolidated in the manufacturing field and many researchers and consultants have argued about the applications in this field. However, the chapter dedicated to the literature review (Chapter 3) reveals how in the health care sector and public administration or public sector there is still not a model universally accepted by the world of research. There are, however, numerous cases of applications of Six Sigma both in the USA and in Europe in the public administration sector but their use is more recent than in the manufacturing field.

The reason why researchers might not yet have outlined a specific model is that the literature tends to apply the model of manufacturing to health care. However, this approach can be placed under discussion in consideration of the differences between manufacturing and public health care especially European public health care. In order to gain real advantages for such a health care system, it is worth analysing, discussing and designing a possible dedicated model and comparing it with the manufacturing one.

The idea of developing a model sinks its roots into a direct analysis and inquiry in the Italian public health care sector. In fact, this latter has a mission and values, a culture, an organisation, strategies and processes that are often very different from the production sector and can be compared with other national health care systems.

According to Van Der Zee and Kroneman (2007), Europe is divided into two big typologies of health care systems. The first one is the so-called National Health Service (NHS), derived from the work of Lord Beveridge, in which the government is the main payer and acts as a strong regulator and controller. The second, derived from the German Chancellor Bismarck, is the so-called Social Security Health care system (SSH) based on a mix of government funding and taxes deducted directly from salaries. Chapters 7 and 8 analyse the differences between the two systems in detail. Italy nowadays belongs to the NHS along with other countries as shown in Table 1.1.

There are slight differences between the two systems; the two most important differences are that the NHS is a little more expensive as a system and usually there is a stronger political influence on the NHS. Countries such as France and

Italy have public health care systems in which there is strong political interference. As discussed in the seventh and eighth chapters, the political influence on health care systems in Italy extends to local authorities such as city councils and regions. However, this particular Italian factor will not be incorporated in the design of the general European model.

Table 1.1: Countries that belong to the NHS and SSH systems

NHS countries	SSH countries
Denmark	Austria
Finland	Belgium
Greece	France
Ireland	Germany
Italy	Luxembourg
Norway	Netherlands
Portugal	Switzerland
Spain	
Sweden	
United Kingdom	

Political influences apart, according to Van Der Zee and Kroneman (2007) and Alesina and Giavazzi (2006), who looked at the different health care systems in Europe, common elements can be found; these common elements justify the use of the Italian health care system as a foundation for the research. First, as discussed in Subsection 1.1.1, European public health care organisations are linked mainly to public funds. Table 1.2 shows the different percentages of gross domestic product (GDP) that EU countries set aside for public health care. Public health care expenditure is high even though the countries are dealing with the EU crisis.

Second, European health care services share many objectives such as patient satisfaction and the reduction of waiting lists, infections and mortalities. To reach these objectives, public health care organisations in countries such as Greece, Italy, Spain, Portugal and even France and the UK, can spend more than their incomes. As discussed in the second chapter, Six Sigma is a model that particularly focuses on cost reduction. How can that approach be applied to European public health care organisations? Only this issue could lead researchers to investigate Six Sigma in European public health care.

Another interesting common element is related to the size and the organisation of hospitals. It has been thought in Europe since the 1980s that the bigger a public hospital the better it will be in terms of performance and cost reduction (McKee and Healy, 2002). This implies that European public hospitals are usually very complex organisations in which departments and administrative structures permeate other departments and administrative structures. Heads of departments run a sort of small-sized company that receives and provides products and services from and to other departments. Similar situations exist in all large European hospitals. How can Six sigma be applied in such systems?

The contracts of employment of doctors and nurses are also similar across Europe, as well as their university backgrounds and trade union schemes (European Council, 1986). These factors could affect skills, organisational climate, roles and rules related to management systems derived from manufacturing systems such as Six Sigma.

According to Alesina and Giavazzi (2006), other common elements that distinguish the European public sector from the manufacturing sector are:

- social or political constraints in the definition of the typologies of services and the levels of quality;
- social or political constraints in the definition of the strategies of the organisation;
- regulations and laws to manage the services;
- situations of monopoly or almost-monopoly on the territory;
- hierarchical organisations with strict rules, roles and responsibilities that are difficult to modify (Mintzberg, 1990);
- internal centres of ‘power’ sometimes not in perfect tune with the top management;
- stronger trade unions involved in the strategic issues.

These elements mean that it is difficult to integrally apply the classical manufacturing Six Sigma model, as delineated by Harry and Schroeder (2000), to the health care sector. However, the discussion above justifies research that starts from the Italian situation. In fact the different public European health care systems have more in common than is believed. The economic and financing assets, many strategic objectives, the organisation, roles and rules, organisational climate and the external relationships with the stakeholders are quite similar across countries.

Thence the research starts with a qualitative inquiry within two Italian hospitals but to make the results more generalisable a second quantitative stage has been carried out in a European context. Indeed the survey in the second stage and its respondents, as discussed in the sixth chapter, are European academics and health care professionals. As shaped in the seventh chapter, the final model is based on ten theoretical principles validated by European health care experts who believe the principles are relevant to European public health care. The generalisability of one of these principles is disputable because it is linked to the typical political situation in Italy.

The goal at the end of this research is to propose a model for the European public health care sector, as well as the way of implementing it, and to compare it with the manufacturing model. The way of implementing the model is the epistemological interpretation of the model. Due to the differences between the US and European systems, the model is designed specifically for the European public health care sector. The model will make a contribution to knowledge by enriching previous works on Six Sigma (see third chapter).

1.1.1 Introduction to the European public sector

Health is a priority for European citizens. Everyone wants to be protected from diseases and all the EU countries spend a part of their GDP on the public health care system. The European health care system is quite different from the American one. People in the USA see health care as a product or service to buy instead of a citizen right and the health care industry is mainly private. During the past decade, expenditure on public health care in the EU has been growing and some countries in 2007 spent over 10% of their GDP on public health care (OECD, 2010). Table 2 shows the expenditure of individual countries in the EU on public health care in terms of percentage of GDP in 2007 (OECD, 2010).

Table 1.2: Expenditure on public health care in the EU in 2007 (OECD, 2010)

Country	**2007**
Austria	10.1
Belgium	10.2
Denmark	9.8
Finland	8.2
France	11
Germany	10.4
Greece	9.6
Ireland	7.6
Italy	8.7
Luxembourg	n/a
Netherlands	9.8
Portugal	n/a
Spain	8.5
Sweden	9.1
United Kingdom	8.4

Each EU country is free to decide their own health policy and strategies but there are common shared values and a strategic framework. For example, first of all there is the right of every citizen to obtain and access quality health care in any country in the EU. The Commission of the European Communities (2007) issued a 'White Paper' defining the Health Care strategy until 2013. In the White Paper, the Commission of the European Communities indicates four principles and three strategic objectives for the coming years:

Principle I: a strategy based on shared health values, in particular universality, access to good quality care, equity and solidarity. It is interesting to note and to better understand public health care organisations that the Commission in the White Paper states:

Patients' rights, such as participation in decision making and health literacy, should also be taken into consideration in Community health policy.

In this way European citizens are invited to participate in political discussion on health care, and social matters become more important than economic and financial matters. Health capital differs from any other human capital, especially in Europe.

Principle II: health is the greatest wealth and it is fundamental in order to improve economic productivity. According to the White Paper:

The Commission and the Member States must develop a programme of analytical studies of the economic relationships between health status, health investment and economic growth.

Principle III: health in all policies. Synergies must be created with other sectors such as environment, research and regional policies, and those policies regulating pharmaceuticals, foodstuffs and anything else that is vital for health.

Principle IV: strengthening the EU's voice in global health. The principles are tied to three strategic objectives that define the Community action plan in health care until 2013.

Objective I: fostering good health in an ageing Europe.

Objective II: protecting citizens from health threats.

Objective III: supporting dynamic health systems and new technologies. For example, Six Sigma could bring the European health care system towards this dynamic vision and introduce a new approach.

Therefore it seems that the Commission and the European countries are trying to reach strategic objectives based on, first of all, patient satisfaction and a high quality standard all around Europe. Economic and financial issues are surely important, especially in such a crucial period, but they do not represent the only or main target. Public health care organisations and their processes for the coming years should try to maximize customer satisfaction as well as clinical results and staff professionalism. According to the Commonwealth Fund (BBC, 2010), taking into account five areas of performance such as quality efficiency, access to care, equity and healthy lives in the seven more industrialised countries, the first three nations in the ranking are European. The Netherlands, UK and Germany lead the ranking and they perform better than New Zealand, Canada and the USA.

At the same time health care organisations should try to reduce costs, avoid cutting down important investments in technologies, employees and medicines. Six Sigma and its tools, as explained in the second chapter, can potentially help the organisations to reduce the cost structure, even if patient satisfaction is always the first objective.

In such a European scenario, the Italian health care system deserves an in-depth discussion as shown in the eighth chapter. Indeed, in Italy the influence of local authorities on strategic health care objectives and on the appointment of the heads of departments inside the organisations is stronger than in other countries. However, expenditure on health care as part of GDP, the view that health care is a right and the adhesion to the previously mentioned principles of the EU are surely issues common to all Europe.

1.2 Structure of the thesis

In order to achieve the main aim, the thesis has been conducted in two stages. Although the thesis is primarily deductive, the first stage is typically inductive and the second one is deductive. A third minor stage based on qualitative–inductive methods helps to put the finishing touches to the proposed model.

Figure 1.1 shows the flow of the chapters and the research phases. The research starts with the first chapter in which the subject of the research and the boundaries around it are defined. Chapter 1 also explains why the issues are important to the scientific management community and the different stakeholders. Chapter 2 deals with the consolidated model for the manufacturing sector, introducing the DMAIC pattern, its tools and organisation. After having dealt with the consolidated manufacturing model, the relevant Six Sigma literature in both manufacturing and health care sectors is reviewed in Chapter 3. At the same time Chapter 3 tries to explain and 'localise' Six Sigma 'philosophically'. Six Sigma is compared with BPR, TQM and Lean Thinking in order to better understand the epistemological assumptions of Six Sigma for the manufacturing sector.

Chapters 4 and 5 represent the 'core' of the research. In particular, Chapter 4 shows the research methodology, the underpinning that legitimates the choice of methodologies and the epistemological issues (Bryman, 1988). The research is grounded on a triangulation between qualitative, quantitative and one more qualitative inquiries. Chapter 6 is dedicated to the validation of the hypotheses generated by the qualitative inquiry including grounded theory.

Figure 1.1: Chapter and research phase flow

Outcome/Link	
	Chapter 1 – Definition of the subject of the research
Justification of the research	
	Chapter 2 – The theoretical principles for Six Sigma in manufacturing
Discussion of the manufacturing model	
	Chapter 3 – Six Sigma literature review and Six Sigma philosophically
Inputs for the qualitative inquiry. Ontological and epistemological location of Six Sigma	
	Chapter 4 – Research methodologies
Seeking the right methodologies	
	Chapter 5 – Data gathering and process analysis using grounded theory
Analysing data gathered and development of the preliminary model	
	Chapter 6 – Validation of the hypotheses
Validation of the hypotheses	
	Chapter 7 – The Six Sigma model for health care
Development of the final model	
	Chapter 8 – Understanding the differences
Discussion of the differences between manufacturing and European public health care	
	Chapter 9 – Conclusions and agenda for future research

Lastly, the model is developed in Chapters 7 and 8, the differences between the model and the manufacturing model are discussed, and the features of the Italian system are described. Conclusions and reflections, contribution to knowledge and agenda for future research are discussed in the last chapter.

1.3 Contribution to knowledge: the importance of a European public health care model for the scientific community and other stakeholders

According to the review of various authors' papers (see third chapter), the research regarding Six Sigma for the health care sector has reached the following results.

First, it seems that some authors believe that the manufacturing model can be applied to public health care with small or no variations. Then, especially after 2002, many authors started arguing about the so-called Lean Six Sigma that uses tools borrowed from other management systems, particularly Lean Thinking. Furthermore, nobody investigated how the organisational climate and the rules and skills of doctors and nurses can affect Six Sigma in European public health care. In European public health care it is believed, however, that results could be improved and, above all, that the definition of a specific model could be reached. This view is held particularly in Italian public health care although it has many aspects that differ from other European countries.

This thesis attempts to make new contributions to the literature by primarily bringing knowledge to the stakeholders of public health care in the academic field and secondarily to the practitioners. The first contribution is a roadmap for shaping a new Six Sigma model for European public health care. This model enriches previous works on Six Sigma (see third chapter) by analysing the way to implement Six Sigma, the goals to achieve, the organisation in the European public sector, the skills of the dedicated teams (i.e. Black and Green Belts) and the tools. The research also tries to evaluate whether or not there are differences in the DMAIC pattern (see Chapter 2).

The second contribution is positioning the proposed model in a larger context of organisational and management research. Indeed, once designed, the model could raise a new debate and consequently further current research. For instance, the model focuses particularly on European public health care and it can be compared or discussed in an analysis of different health care systems.

Through the analysis of two Italian public hospital case studies in which Six Sigma is applied and through gathering data and information from the literature review, a new model can be built. Qualitative and quantitative methods as well as grounded theory have been used. Chapter 3 shows that the academic world has not yet affected the possibility of introducing such a model. The stakeholders related to the consulting field have, however, been active; in fact, part of the reviewed authors belongs to this sector. The introduction of a model for public health care therefore certainly affects the consulting field, even if the thesis is not intended as a guideline for the application of Six Sigma in the Health Care sector dedicated to practitioners.

1.3.1 The scope and boundaries of the research

The built model will be formed by theoretical principles linked together by the means of grounded theory and by epistemological aspects that represent the way for implementing the model. In the next chapters the research aims to define:

- the general organisation of Six Sigma in health care;
- the strategic aspects that can affect the Six sigma projects;
- the different organisational climate, culture, rules and responsibilities for Six Sigma in European public health care;
- the differences between the Italian health care system and European systems;
- what kind of tools are better inside the DMAIC pattern;
- the possibility to improve the Six Sigma model through tools borrowed from other systems of excellence (e.g. Lean Thinking and TQM).

The boundaries, however, limit the research to specific areas without going into the merits of others. Specifically, the research first analyses the organisation which can manage the Six Sigma projects in European public health care, without going into the merits of what is the best organisational model for public health care in general; indeed the purpose of the research is not to make a specific organisational model for public health care but a specific one related to Six Sigma management. In addition, the research tries to understand whether the universally accepted and established DMAIC tools (see next chapter) would be suitable for public health care.

The research also attempts to understand whether there is a different and specific way to manage the DMAIC pattern for health care. The research does not enter the technical discussion of how to apply specific statistical or managerial tools because there already exists extensive literature on the application of tools in health care and it is therefore unnecessary to enter into this area. However, it is interesting to understand what tools can be added, eliminated or stressed as suggested by some authors. Furthermore, the research goes into the substance of the management of the teams dedicated to Six Sigma, in terms of components of the team, kind of skills, education, training and roles and responsibilities. It is important to understand, for example, the difference between the skills that these members should possess in the manufacturing sector and in the European public health care sector.

The model will be designed using the validated differences from the manufacturing model and it is presented and discussed in the seventh and eighth chapters. The final model could be also compared in the future with other health care systems especially the US health care system. It is well known that in the USA the health care sector is dominated by the private sector. This dominance changes the mission and the organisation of a typical provider in health care. For example, the incomes are from both the government and private insurers (Chua, 2006) therefore the strategic objectives are more tied to the economic and customer satisfaction results. In many European countries, such as Germany, Italy and France, it is important to reach social and political goals as well, and this could affect the way resources are managed and the organisation of improvement projects and the entire model.

1.4 Conclusions and next steps

This first chapter has defined the subject of the research and drawn some boundaries around it. The issue is very important for the academic sector and secondarily for the practitioners. There is not, currently, a complete Six Sigma model for European public health care that shows the differences with respect to the classic manufacturing model and a way to implement it. In addition, the model has to take into account the social and political aspects that can affect the organisation of the model. Before addressing the content of the research it is essential, however, to dwell on the general principles of Six Sigma, stressing, in particular, those concepts and tools that are taken, analysed and put into question for the creation of the model. The next chapter will show how in the manufacturing sector Six Sigma is well established and very few of its details are now disputable. Furthermore, in the third chapter, through a deep literature review and a comparison with other management systems for excellence such as TQM, BPR and Lean Thinking, we will try to find the way that Six Sigma is implemented in the manufacturing sector. This proposed way is underpinned by ten epistemological assumptions that will be compared with the similar European public health care assumptions.

Chapter 2 – The theoretical principles for Six Sigma in manufacturing

2.1 Introduction

In this chapter, the origins and framework of Six Sigma are discussed and in particular what is consolidated in the manufacturing sector. This chapter is deepened in the third chapter where all the Six Sigma literature will be reviewed.

Carl Frederick Gauss (1777–1855) introduced the normal curve and the concept of standard deviation or sigma (Gauss, 1966). Six Sigma as a measurement standard in product variation can be traced back to the 1920s when Walter Shewhart showed the correlation between levels of sigma from the mean and the defects produced in a process. When a range around a defined target is fixed it can be statistically demonstrated that the more the number of sigma stays inside the range, the less the probability that the outcome is a failure. Failure means that the outcome is outside the range and consequently the products or services are defective. Many measurement standards entered the scientific and management literature later but the term 'Six Sigma' was coined by a Motorola engineer named Bill Smith. Motorola is an American multinational telecommunications company based in Schaumburg, Illinois, which was divided in 2009 into two independent public companies

In the early and mid-1980s with Chairman Bob Galvin, Motorola engineers decided that the traditional quality levels that measured defects in thousands of opportunities did not provide enough quality results; instead, they wanted to measure the defects per million opportunities (DPMO). Motorola developed the new Six Sigma standard, created the methodology and the required cultural change associated with it. Six Sigma helped Motorola realise powerful bottom-line results in the entire organisation; in fact, Motorola documented more than $16 billion in savings because of Six Sigma efforts. Since then, hundreds of companies around the world have adopted Six Sigma as a way of doing business. This is a direct result of many of USA's leaders openly praising the benefits of Six Sigma: leaders such as Larry Bossidy of Allied Signal (now Honeywell) and Jack Welch of General Electric Company (Harry and Schroeder, 2000).

2.2 Six Sigma as an Excellence Management System

Six Sigma is a management system similar to TQM, BPR or Lean Thinking. It is considered a system for reaching business excellence (Klefsjo *et al.,* 2001; Adebanjo, 2001; Starbird, 2002) and it focuses on a precise application pattern called DMAIC (Klefsjo *et al.,* 2001, Revere and Black, 2003). It improves customer satisfaction along with all organisational performance (Przekop, 2003). The main worldwide companies use Six Sigma, especially those quoted in Wall Street (Pande *et al.*, 2000; Senapati, 2004).

After Motorola, other important companies such as GE, Allied Signal, Caterpillar and many others chose Six Sigma and obtained significant savings in terms of 'Cost Of Poor Quality' (COPQ).

Some authors (e.g. McAuley *et al.,* 2007) dealt with neo-modernist organisation theory, introducing the 'new-wave management' (Wood, 1989).
These authors see Six Sigma and other similar management systems from a highly critical perspective. Six Sigma can impose onto organisations increased levels of control that deny the possibility of autonomy and professional independence. This issue along with Six Sigma and its ontological and epistemological position are discussed in the third chapter. In this chapter it is also compared with other management systems that seem to have many similarities such as TQM, BPR and Lean Thinking.

2.3 The classic model for the manufacturing sector

Since the late 1990s innumerable articles have been written on Six Sigma. Harry and Schroeder's (2000) model is now hailed as the classical Six Sigma model for the manufacturing sector. The first author, in particular, as an ex-

Motorola manager, has been able to analyse the model directly in the organisation that conceived it, and used it better. In their book, *Six Sigma: The Breakthrough Management Strategy Revolutionizing the World's Top Corporations*, Harry and Schroeder delineate the basic model that is used today, substantially, in all manufacturing organisations.

In an approximate way, Harry puts in correlation the sigma level of a process (any process, from marketing to customer care) with the number of defects and the CPQ to which the organisation is subjected, as shown in Table 2.1.

Table 2.1: Correlation among sigma of a process, DPMO and CPQ

Sigma level	DPMO (Defects Per Million Opportunities)	CPQ (Cost of Poor Quality)
2	308.537	Not applicable
3	66.807	25–40% of turnover
4	6210 (typical company)	15–25% of turnover
5	233	5–15% of turnover
6	3, 4	< 1% of turnover

From Harry and Schroeder, 2000

This table is very important in the Six Sigma model because it 'certifies' the achievement of a determined level of sigma both on a specific project and process, up to the whole organisation. Continually obtaining higher levels of sigma, the organisation numerically shows the reduction in the CPQ and obtains a precise saving.

2.3.1 The Six Sigma DMAIC pattern

In the classical approach there are five stages for the realisation of strategic projects in Six Sigma and they are known as the acronym DMAIC (Pande *et al.*, 2000; Breyfogle, 2003; Lynch *et al.*, 2003; Pyzdek, 2009):

- D – Define,
- M – Measure,
- A – Analyse,
- I – Improve,
- C – Control.

It is not difficult to connect the 5 phases of DMAIC with Deming's (1982) classical approach: Plan – Do – Check – Act (PDCA). According to Harry and Schroeder (2000), the five stages are applicable to different levels of the organisation:

- Business,
- Operations,
- Process.

In fact, every stage of DMAIC represents the deployment of the precedent according to the classical management system deployment (Akao, 1991; Kaplan and Norton, 1996). The D of DMAIC, for instance, expects the definition of long- and medium-term objectives from the business level in a Business Plan. The medium- and long-term objectives are turned into a definition of objectives of a brief period (one year) for the operations level. The objectives of the brief period also define the CTQ of the processes connected to the attainment of the objectives as shown in Figure 2.1. This strict link between strategies and CTQs is one of the changes introduced by Six Sigma.

At the process level, the Six Sigma DMAIC methodology can be thought of as a path for problem solving and continuous improvement. Most companies begin implementing Six Sigma using the DMAIC methodology, and later add the Design for Six Sigma (DFSS) methodology when the organisational culture and experience level allows projects to be conducted in the technical departments (rarely applied in Public Health Care).

For each phase, a team formed by a Black Belt and several Green Belts (see section 2.3.2) uses classical tools derived from the quality world. Many authors, especially consultants, list these tools that are by now well established for manufacturing (Pande *et al.*, 2000; Breyfogle, 2003; Snee and Hoerl, 2003; Pyzdek *et al.* 2009; George, 2002).

Figure 2.1: The deployment from the business plan

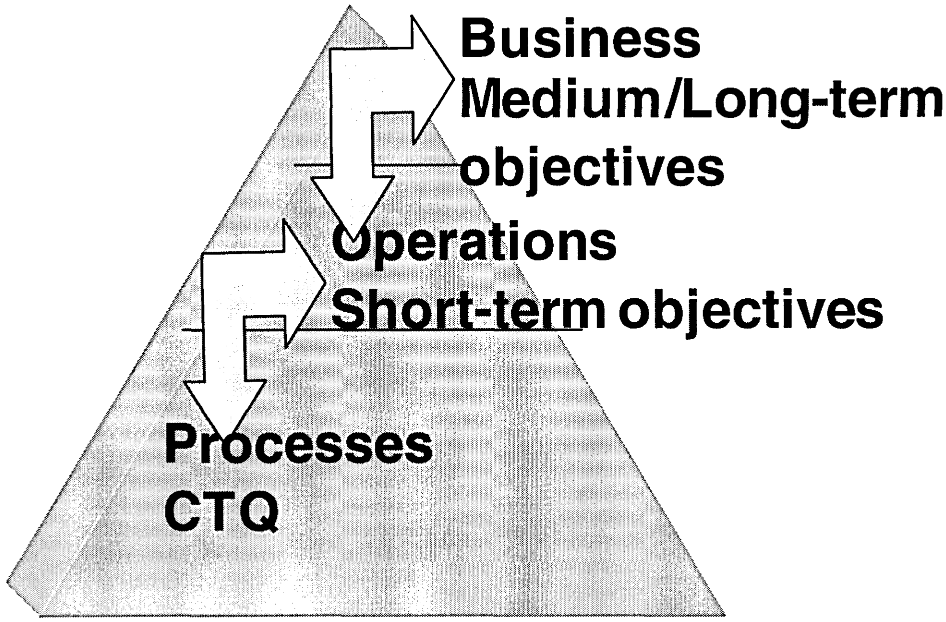


Table 2.2 synthesises the tools used in the classical manufacturing model in correspondence to the DMAIC stages. It can be noted that Six Sigma did not invent any new tools rather Six Sigma just better arranged the tools derived from TQM and Lean Thinking.

Table 2.2: DMAIC and tools used in the manufacturing sector

DMAIC Phase Steps	**Tools Used**
D - Define Phase: Define the project goals and customer (internal and external) needs.	
□ Define Customers and Requirements (CTQs) □ Develop Problem Statement, Goals and Benefits □ Identify Champion, Process Owner and Team □ Define Resources □ Evaluate Key Organizational Support □ Develop Project Plan and Milestones □ Develop High Level Process Map	□ Project Charter □ Process Flowchart □ SIPOC Diagram □ Stakeholder Analysis □ CTQ Matrix Definition □ Quality Function Deployment (QFD) – Kano Analysis
Define Tollgate Review	
M - Measure Phase: Measure the process to determine current performanc ; quantify the problem.	

□ Define Defect, Opportunity, Unit and Metrics □ Detailed Process Map of Appropriate Areas □ Develop Data Collection Plan □ Validate the Measurement System □ Collect the Data □ Begin Developing Y=f(x) Relationship □ Determine Process C pability and Sigma Baseline	□ Data Collection Plan/Example □ Benchmarking □ Measurement System Analysis/Gage R&R □ Voice of the Customer Gathering □ Cp, Cp
Measure Tollgate Review	
A - Analyse Phase: Analyse and determine the root cause(s) of the defects.	
□ Define Performance Objectives □ Identify Value/Non-Value Added Process Steps □ Identify Sources of Variation □ Determine Root Cause(s) □ Determine Vital Few x's, Y=f(x) Relationship	□ Histogram □ Pareto Chart □ Time Series/Run Chart □ Scatter Plot □ Regression Analysis □ Cause and Effect/Fishbone Diagram □ 5 Whys □ Process Map Review and Analysis □ Statistical Analysis □ Hypothesis Testing (Continuous and Discrete) □ Non-Normal Data Analysis
Analyse Tollgate Review	
I - Improve Phase: Improve the process by eliminating defects.	
□ Perform Design of Experiments □ Develop Potential Solutions □ Define Operating Tolerances of Potential System □ Assess Failure Modes of Potential Solutions □ Validate Potential Improvement by Pilot Studies □ Correct/Re-Evaluate Potential Solution	□ Brainstorming □ Mistake Proofing □ Design of Experiments □ Failure Modes and Effects Analysis – FMEA □ Simulation oftware
Improve Tollgate Review	
C - Control Phase: Control uture process performance.	
□ Define and Validate Monitoring and Control System □ Develop Standards and Procedures □ Implement Statistical Process Control □ Determine Process Capability □ Develop Transfer Plan, Handoff to Process	□ Process Sigma Calculation, Cp - Cpk □ Control Charts (Variable and Attribute) □ Cost Savings Calculations □ Control Plan

Owner □ Verify Benefits, Cost Savings/Avoidance, Profit Growth □ Close Project, Finalize Documentation □ Commun cate to Business, Celebrate	
Control Tollgate Review	

Table 2.2 shows, in a precise way, how a project of improvement that follows the DMAIC stages needs knowledge of advanced statistic tools such as ANOVA and Design Of Experiments (DOE). The projects, because of their nature, involve a team for a period varying from a few months up to one year, or even more, according to the typology of saving required.

The power of the Six Sigma DMAIC pattern lies in the structure and the rigour of the approach. The team of Black and Green Belts uses the most important tools for the kind of project.

2.3.2 The roles in Six Sigma

The players traditionally involved in Six Sigma projects are (Brue, 2000; Pande *et al.,* 2000; Snee and Hoerl, 2003):

- **Senior Champion or Sponsor** (Executive Leader)

He or she is the CEO or the Head of Office that decides to introduce the strategic model Six Sigma. The Senior Champion appoints one or more:

- **Champions**

Champions, together with the Senior Champion, decide the projects and the strategic objectives on which Six Sigma is applied. The Champion appoints the:

- **Master Black Belt**

This is a manager or a consultant that manages the training and works as 'coach' on the Six Sigma projects. The principal assignment is to ensure that the whole organisation receives the appropriate knowledge on the methods and tools. The Master Black Belt and the Black Belt decide the projects and the processes on which to operate that are connected to the objectives decided by the Champion.

- **Black Belt**

The Black Belts are team leaders on specific projects and they manage all the resources and the necessary knowledge for the project. They have, naturally, to know the tools of quality and problem solving well, as well as project management and team building. Every Black Belt manages a team composed of:

- **Green Belts**

They are the operative components of the team devoted to a specific project. Their principal assignment is to follow, day by day, the project and the measures. They have less detailed knowledge of the tools for quality. In the USA and Europe, different organisations have adopted a consolidated scheme for the certification of the Black Belt and Master Black Belt as summarised in Table 2.3.

Table 2.3: Six Sigma training certification

Role	Training
Black Belt (BB)	- Four weeks of training (one week/month) - A week of statistics of base, seven tools and analysis of the data - A week of DOE, FMEA, QFD - A week of advanced statistic control for quality - A week of project management, management and team motivation - Project Six Sigma to be brought ahead with a MBB and one autonomously
Master Black Belt (MBB)	- Certified following 20 projects with success as BB

2.4 Lean Six Sigma in the service industry and health care

Since early 2000, Six Sigma has begun to find application in non-manufacturing processes, such as engineering and product design (Design For Six Sigma), marketing, accounting, finance and so on. Within a few years, Six Sigma has been used as a model in service companies in the sectors of finance (banks, insurance), shipping and delivery, education, government offices, public utilities and, last but not least, in health care. Since 2000, a proliferation of articles, often issued by consultants, describes the application of DMAIC in service industries and in health care without, however, delineating important differences and, above all, the peculiarities of the services. The DMAIC application is the same as the classical manufacturing model of Harry and Schroeder (2000), without taking care of the typical processes of the services. As expressed in the first chapter, the service industry and particularly Public Health Care have their own organisation, their own culture and their own kind of management.

George (2003) published *Lean Six Sigma for Service* that, in a not entirely complete way (see considerations in the following chapter), tries to complete a model for the services sector. In synthesis, George's text introduces:

- the improvement of the model through the union with the Lean Thinking of Japanese derivation;
- as a result of the point above, new tools to be inserted in the DMAIC approach;
- two levels of improvement projects: Six Sigma projects that eliminate the defects and the variability of processes and Lean Thinking projects that concentrate on the speed of realisation of the service and on the hunting of wastes.

Nevertheless, George does not distinguish between services provided by a public organisation such as a hospital and other services, and he does not suggest specific tools and Six Sigma organisation for health care. The text, therefore, tends to be a whole made up of two models (Six Sigma and Lean Thinking) without delineating a true model for the services.

Other authors have dealt with Six Sigma in health care and their conclusions are analysed in the third chapter that is dedicated to the literature review.

2.4.1 Differences between manufacturing and service industry and health care: implications for Six Sigma application

As discussed in the previous section some authors have started analysing how to apply Six Sigma in the service industry, using at the same time tools borrowed from Lean Thinking. According to George (2003) there are many differences between the two sectors that can lead to different considerations about Six Sigma.

Firstly, the service industry, including public health care, mainly manages 'transactions' instead of physical products. Transaction is a term derived from Information Technology (IT) but it is impossible to track a specific definition. Processes are made of activities, and a transaction is a logic unit of work carried out inside an activity.

There are important differences between managing a physical product and a transaction (Parasuraman and Grewal, 2000). Even if the transactions can be as standardised and as repeatable as manufacturing activities, they are usually affected by much more variability. Nowadays electronic devices help people to reduce times and mistakes when they manage transactions, nevertheless, the human factor is definitely more important than in manufacturing. A nurse can use bar codes and computers in order to administrate the right drug to the patient on time. However, factors such as courtesy and hospitality for the patient, especially for grave diseases, can make a difference. In the manufacturing sector workers have to use the right machine with the right products and instructions but the worker's mood surely affects the quality of the outcome less.

Another important difference is that in manufacturing a product with some defects can often be reworked or rejected without advising the customer of the situation. This surely increases the cost but, in any case, the customer will not complain about the defect. By contrast, workers in the service industry are often in direct contact with the customer and if something goes wrong the customer perceives it (Antony, 2004). In this case it is too late and it is impossible to 'rework' or redo the service (for instance a professor who has to teach a subject just once, or a surgeon who has to operate on a critical patient).

In addition, performance measures in manufacturing differ from those of service industries. A manufacturing machine can automatically register worker activity and product performance. However, it would be difficult to measure how much time during a day a nurse dedicates to taking psychological care of patients. In public health care the difficulty of this phenomenon is increased by the fact that the services provided are usually different from one patient to another one. In this way it is interesting to analyse how some authors (Moullin and Soady, 2008) focus first on identifying the outcome that matters most to patients instead of a particular pattern or tool. Product requirements can be grouped, whereas individual requirements differ from patient to patient.

The differences discussed above are quite difficult to manage using the classical manufacturing model. Six Sigma is a sort of clockwork model where the boundaries of a problem have to be very clear and measurable. The majority of the DMAIC tools, including advanced statistical ones, are more suitable for repeatable activities managed in a large quantity. Besides this, statistical tools need precise data gathering and the data sampled must not have bias due to 'psychological' factors. Maybe this is one of the reasons why Six Sigma has started borrowing tools from Lean Thinking as discussed in Section 2.3. For instance, if a public hospital wants to improve patient satisfaction concerning the kindness of nurses and doctors inside a long-stay inpatient department, advanced statistical tools are not so useful. Indeed, in this case it is even difficult to measure satisfaction using a questionnaire. Macdonald *et al.* (1988) tried to measure patient satisfaction with life in a long-stay psychiatric hospital. They had to develop a specific questionnaire, finding out that levels of satisfaction varied significantly among wards. According to Macdonald *et al.* patients can express personal views about their own conditions which should be useful in planning improvements in care. In this particular case statistics and even the DMAIC pattern cannot be useful.

On the contrary, advanced statistical tools can be very useful if inside a ward doctors want to analyse whether or not temperature, humidity and other factors can influence the recovery time from a disease. In this case data can be more easily gathered avoiding psychological and personal influence factors.

2.5 Conclusions and next steps

Six Sigma is a real and consolidated model in the manufacturing sector and leads companies towards excellence as discussed in the next chapter. It is considered a management system particularly oriented to cost reduction and could be claimed as a New-Wave management model. Indeed, it tries to reduce COPQ inside the processes by measuring and improving the sigma level around the target. The improvement teams follow a precise and rigorous pattern called DMAIC. For every DMAIC stage teams can use several tools derived especially from quality management; some of them are very advanced statistical tools. Within the team a certified Black Belt acts like a team leader and Green Belts are fundamental members as well. In order to obtain Black or Green Belt certification members have to acquire statistical and managerial skills. The results and savings of each project are certified as well for a management review.

Six Sigma has recently been implemented in the service industry and health care but using the same manufacturing model. Section 2.4.1 has lighted important differences between manufacturing and service industries, including health care.

The next chapter tries to retrace Six Sigma history through a literature review. This latter also locates Six Sigma philosophically, defining the way of implementing it and its epistemological assumptions. Finally, yet importantly, in the next chapter Six Sigma is compared with the most important management systems such as TQM, BPR and Lean Thinking. Lean Thinking has been introduced to Six Sigma and it has borrowed some news tools derived from the Toyota Production System. It is important to analyse and discuss Lean Thinking because Public Health Care has been using the particular tools born from the so-called Lean Six Sigma.

Chapter 3 – Six Sigma literature review and Six Sigma philosophically

3.1 Introduction

The previous chapter described Six Sigma and the theoretical principles of the manufacturing Six Sigma model. Six Sigma is considered a management system for excellence and it is based on the DMAIC pattern. Six Sigma uses teams made up of personnel with specific skills, in particular Black and Green Belts. However, European Public Health Care is a type of organisation in which personnel, as well as in the service industries, normally do not use advanced statistical tools. In addition, European Health Care is typically managed by following the dictates of laws and regulations imposed from outside due to the importance of patient health as directly demanded by the EU. Furthermore, Public Health Care is more affected than manufacturing by aspects such as organisational climate, skills, politics and others. European Public Health Care requires, therefore, a Six Sigma model with its own logic.

3.2 The structure of the chapter

This chapter has two specific scopes and consequently it is divided in two parts. The first part of the chapter tries to locate philosophically what Six Sigma is, especially in the manufacturing sector. In this way Six Sigma will be compared with other management systems for excellence such as TQM, BPR and Lean Thinking. The results will also be used in the seventh chapter in order to compare Six Sigma in the manufacturing and European Public Health Care sectors.

The second part reviews Six Sigma literature in order to understand what is 'the state of the art' of the literature dedicated to both the manufacturing and the Health Care sectors. Many books and articles discuss Six Sigma and many of these are prepared by consultants rather than by academic researchers. The question that arises is whether such literature outlines in some way a model for

Health Care or Public Health Care similar to the model previously discussed for manufacturing. For this purpose the second part review the main literature but neglect articles or books without any, or a poor, research method.

3.3 A philosophical comparison between Six Sigma and other management systems in the manufacturing sector

The first part of the chapter tries to 'locate' Six Sigma in a philosophical way. In particular, it is fundamental to understand what the differences are between Six Sigma and other well-known management systems, as well as the possibilities of integration with them. The philosophical assumptions are focused on the manufacturing sector and in the last chapter will be compared with Health Care features.

3.3.1 Why TQM, BPR and Lean are related to Six Sigma

Six Sigma, TQM, BPR and Lean Thinking are management systems with their own approaches, patterns and tools. They have different origins and they were established in different periods. Six Sigma and BPR were developed in the USA in the 1990s and 1980s, whereas TQM and Lean are Japanese systems and their roots were established in the 1960s. In any case they are alike in some important respects. First of all, Six Sigma is considered a business excellence system and many authors have classified all the four systems as business excellence systems (Carr and Littman, 1990; Ho and Fung, 1994; Jackson and Jones, 1996; Wallace and Kani, 2000; Klefsjo *et al.,* 2001; Starbird, 2002; Goh, 2002). According to the authors in each of the four systems can be found common characteristics such as: continuous improvement, cost reduction, customer satisfaction, people involvement and process approach. It is important to compare Six Sigma and TQM because the latter is considered a sort of 'parent' of Six Sigma; for instance in the previous chapter the DMAIC pattern has been criticised because of its similarity with TQM: PDCA and the majority of Six Sigma tools are derived from TQM. The same applies to Lean Thinking: its tools have been included in the DMAIC pattern creating the so-called Lean Six Sigma. But what about BPR? What are the reasons to compare it with Six Sigma? TQM and Lean are taken mainly into account because of their tools and patterns but for BPR there is something different. As discussed in Section 3.7, BPR is very focused on cost reduction and brings a precise top-down pattern (Knights and Willmott, 2000) similar to Six Sigma. In the past decade BPR has unexpectedly lost its appeal whereas Six Sigma, TQM and Lean are still alive and kicking. Perhaps the former has become less applied because of the latter. Last but not least, all the systems try to deal with the rapid changes introduced in the past decades by the new market scenario. According to McAuley *et al.* (2007, p. 150), the new strategies suggested include the creation and communication of a shared vision, the creation of flatter less hierarchical organisations, flexibility and freedom by giving employees autonomy through empowering them, the promotion of entrepreneurship and risk taking amongst managers based upon their reading of the environment and anticipating change, the development of skills of remote management so that management control may be exerted from a distance as well as the introduction of flexible organisations around small groups or teams.

At a first glance all the systems propose similar strategies; this will be discussed in more detail in the following sections.

There are, however, differences between Six Sigma and the other management systems that will be analysed and discussed in the next sections. The review tries to understand these differences in a philosophical way, finding the 'epistemological pillars' of the four systems and consequently the way of implementing them.

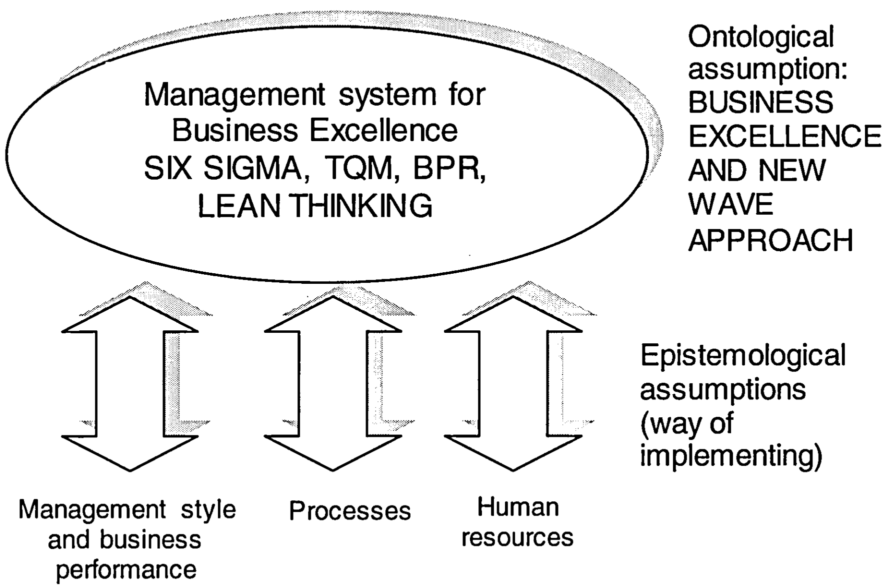
3.3.2 Ontological and epistemological assumptions of the systems

Although the objective of this research is not to go into deep philosophical discussions, it is important to define what ontology and epistemology are in this context. Ontology refers to the nature of beings and epistemology to the ways by which knowledge is created to understand the nature of beings (Lukas, 1978; Sartre and Priest, 2001).

Ontologically, analysing the nature of being, it can be assumed that Six Sigma, TQM, BPR and Lean Thinking are management systems for the previously quoted 'excellence' (see Figure 3.1). Six Sigma, as well as the other systems, tries to respond to the rapid changes of the new marketing scenario. Excellence is a particular a state of being in order to answer the new challenges even in Public Health Care. According to Starbird (2002), inside Six Sigma the keys to excellence are related to identify core processes, customer needs and measures, drive performance trough reporting for management and integrate championing of active project. It is a new way of managing that in organisation theory can be related to the theory Z (England, 1983), with a stronger emphasis on cultural control. In this way Six Sigma, along with the other systems, can be ontologically compared with the new-wave management especially for the new strategies discussed in section 3.3.1.

Thus, Six Sigma, BPR, TQM and Lean Thinking are basic categories of being (Campbell, 1974) within 'excellence' and their similarities can be analysed by epistemological assumptions. Epistemology concerns the nature and the scope of knowledge (Hay, 2008), how the knowledge is created, and in this case epistemology is the way of knowing or improving the implementation

Figure 3.1: Ontological and epistemological assumptions for the systems



Adapted from Chiarini (2011)

of the four different ways towards excellence. After determining the epistemological assumptions of the four management systems (i.e. Six Sigma, TQM, BPR and Lean Thinking) the assumptions will be compared in order to understand differences, similarities and in particular whether or not they can be integrated. Six Sigma is analysed in more detail because it is the benchmark by which the three other systems will be compared, consequently Six Sigma's epistemological assumptions will be the base for the discussion.

3.3.3 Six Sigma epistemological justification and assumptions

Before dealing with the Six Sigma epistemological assumptions, its epistemological justification should be discussed. The way of implementing Six Sigma has a strong emphasis on quantitative issues. Starting from the strategies, everything from the management style to human resource management needs to be measured. This emphasis on the quantitative has been analysed and discussed by several authors (Antony and Banuelas, 2002; Przekop, 2003; Breyfogle, 2003; Gijo and Rao, 2005; Ladani *et al.,* 2006).

Harry and Schroeder (2000) analysed several manufacturing case studies and claimed that there is a quantitative link among the strategies, the operations and the processes of a company that wants to implement Six Sigma. The team efforts and results should also be measured in order to understand and certify the savings achieved.

If the way of implementing Six Sigma has a strong emphasis on quantitative aspects, then it is not so clear what the epistemological assumptions of the system are and how they can be compared with TQM, BPR and Lean Thinking.

Epistemological assumptions of the systems were found through a literature review of academic literature in particular. Literature about Six Sigma, TQM, BPR and Lean Thinking is extensive and during the past two decades many authors have investigated dimensions such as management style, results, processes and human resources management in detail (Chiarini, 2011). Assumptions have been categorised into three dimensions to allow better comparison of what the literature offers concerning the four systems:

- *management style and business performance*, how top and senior managers define their strategy and develop it into organisation processes, what the expected results are;

- *processes*, what kind of tools the management system uses, patterns and specific paths for the projects, skills and rules;
- *human resources*, how employees are involved and what kind of skills they need.

The results of this literature review are described and summarised in the next sections.

From the review of Six Sigma literature, ten 'epistemological pillars', broken down into the three above-mentioned dimensions, were found (see Table 3.1). The ten Six Sigma assumptions are important to understand the general model on which Six Sigma is based and the way to implement it. The research does not analyse Six Sigma tools. Several authors have discussed Six Sigma and the literature describes its tools and in what circumstances they can be applied. The ten assumptions lead, in an original way, through epistemological discussion about the Six Sigma system or model, how and where this model can be allocated, and compares it with the others. In addition, the ten assumptions better show the quantitative nature of the model.

3.3.3.1 The first assumption: Six Sigma improves business performance in general, cost and COPQ reduction model

Coronado and Antony (2002) claimed that Six Sigma reduces exponential defects that affect the COPQ. Since the first important paper and book on Six Sigma (Harry, 1998; Harry and Schroeder, 2000), practitioners and academics have dealt with the cost reduction objective and it can be asserted that Six Sigma leads mainly to reduction of poor quality cost. The DPMO concept is not just a slogan but also a very grounded way to measure how successfully Six Sigma is implemented. According to the first assumption, Six Sigma can also improve business performance in ways ranging from security to safety and environmental management.

Six Sigma is becoming a cornerstone philosophy (Quinn, 2002) because it has been demonstrated 'on the field' that Six Sigma can improve business performance in many ways and, in the final analysis, company margins. The famous GE's CEO, Jack Welch, was very convinced that Six Sigma has an

Table 3.1: Six Sigma epistemological pillars

Dimension	Epistemological assumption
Management style and business performance	1) Improves the business performance in general, cost and cost of poor quality (COPQ) reduction model 2) Requires visionary top management and high commitment and involvement
Processes	3) Reduces variation within the processes 4) Requires focus and capture of the voice of the customer 5) Focuses on improving processes of the whole organisation through DMAIC approach 6) Uses all kinds of tools derived from quality and other management systems 7) Short- and medium-term improvement project but long-term cultural change
Human resources	8) Involvement of employees. Team oriented and use of certified Black and Green Belts 9) Requires skills based on statistics and data 10) Self-empowerment and responsibility

infinite capacity to improve everything (Slater, 1999). But what are the performances that Six Sigma can improve? According to several authors (Harry, 1998; Harry and Schroeder, 2000; Coronado and Antony, 2002; Klefsjo *et al.*, 2001; Wiper and Harrison, 2000; Antony and Banuelas, 2002; Antony, 2004), Six Sigma is mainly dedicated to COPQ reduction but other kinds of business performance can be affected.

The review of the literature shows that Six Sigma projects can be dedicated not only to product quality, but also to: supply chain management (Lee and Whang, 2005), information security management, environmental management system and human resources (Wiper and Harrison, 2000) and many other company sectors. Six Sigma enables organisations to increase profits and business performance in general, eliminating defects in everything a company does.

3.3.3.2 The second assumption: Six Sigma requires visionary top management, and high commitment and involvement

Six Sigma is surely a long-term journey that will change the company's DNA. According to Harry and Schroeder (2000), Six Sigma has a specific deployment starting from the top management who should define strategic objectives linked to a business plan and afterwards develop the objectives into projects. Top and senior management should also review Six Sigma results. Inside top management a 'sponsor' and a 'champion' are supposed to manage the company as a whole towards Six Sigma. Hence, without a clear and well-noticed top-management commitment Six Sigma can fail after a few months of implementation. In addition, leadership and strategic management for Six Sigma should be 'visionary' (Westley and Mintzberg, 1989) because culture and charisma can easily move strategies to processes. Several authors wrote about this important issue for an effective and long-lasting Six Sigma application, in particular Harry and Schroeder (2000), Henderson and Evans (2000), Halliday (2001), Coronado and Antony (2002), Antony and Banuelas (2002), Linderman *et al.* (2003).

3.3.3.3 The third assumption: Six Sigma reduces variation within the processes

Six Sigma is very problem-solving oriented and the DMAIC projects should reduce variation within the processes (Antony and Banuelas, 2002). Reducing COPQ is strictly linked to reducing the variation around the expected target of each process. This was one of the first axioms established by Harry and Schroeder (2000). Companies that launch Six Sigma programmes cannot define CTQs according to strategies and persist into reducing variation around the targets. Therefore, every Six Sigma improvement project is a journey in pursuit of the root causes of the variation. To analyse and identify root causes the teams sometimes have to use advanced statistical tools as explained in the eighth assumption.

3.3.3.4 The fourth assumption: Six Sigma requires focus and capture of the voice of the customer

Six Sigma is an excellence model that aims to reduce COPQ as seen in the first assumption. It is well known how COPQ is usually divided into 'internal error cost' and 'external error cost'. Harrington (1986) was the first to introduce a complete classification of poor-quality cost. In his famous book *Poor-Quality Cost* (1986, p. 5) Harrington wrote:

> *Poor-quality cost is defined as all cost incurred to help employees do the job right every time and the cost of determining if the output is acceptable, plus any cost incurred by the company and the customer because the output did not meet specifications and/or customer expectations.*

When the product/service does not meet customer expectations, the company suffers external error cost such as warranty costs, returned goods and penalties. Six Sigma aims to reduce errors in a very measurable way, including external error.

To avoid external errors the company should listen to the customers and capture 'spoken', 'unspoken' and 'delightful' expectations (Kano *et al.*, 1984). This is what Six Sigma does well, especially through Quality Function Deployment (QFD): a tool used in the first stages of the project (Pyzdek, 2003; Yang and El-Haik, 2009).

3.3.3.5 The fifth assumption: Six Sigma focuses on improving processes of the whole organisation through DMAIC approach

The first and the second assumptions have introduced Six Sigma as an excellence model that aims to improve business performance. The implementation should be conducted within the entire organisation through the DMAIC pattern. Henderson and Evans (2000), Hahn *et al.* (2000), Antony and Banuelas (2002) and Antony and Coronado (2002) analysed the critical success factors of implementing Six Sigma and they claimed that supplier processes could also be improved to maintain reduced costs and reduced variability. To be successful, suppliers have to evolve towards Six Sigma and be involved in Six Sigma programmes. To simplify the approach companies sometimes launch Six Sigma in a few departments or processes (Pande *et al.*, 2000). This could cause trouble inside a company because processes are linked together and performance improvements are reached when all the processes work in unison. However, this situation is typical of many management systems from the simple ISO 9001 to Lean Thinking, BPR and European Foundation for Quality Management (EFQM) (Bendell, 2005; Ricondo and Viles, 2005; Bendell, 2006). The DMAIC pattern is perhaps the most important part of Six Sigma DNA (Byrne and Norris, 2003). Companies that are implementing Six Sigma declare that DMAIC is unique and it helps them to carry out the projects without failures. Indeed every stage, from Define to Control, is validated through a 'tollgate' check that can stop the project if the result stage is not what is expected.

3.3.3.6 The sixth assumption: Six Sigma uses all kinds of tools derived from quality and other management systems

Within the DMAIC pattern, as previously described, Six Sigma teams can use numerous tools dependent on the scope and the kind of stage. It is quite impossible to list all the tools but Six Sigma inherits the well-known quality control and management tools (Klefsjo *et al.*, 2001; Pyzdek, 2003; Dahlgaard and Dahlgaard-Park, 2006) including advanced statistical tools. Six Sigma inevitably encountered Lean Thinking and its tools derived from the Toyota Production System (Ohno, 1988). George (2002) was the first to invent 'Lean Six Sigma' and since this 'encounter' Six Sigma has started to add some Lean tools (Hoerl, 2004). The DMAIC toolset is very open and can surely be enlarged in the future (Tang et *al*., 2007).

3.3.3.7 The seventh assumption: short- and medium-term improvement projects but long-term cultural change

Six Sigma projects are based on the DMAIC path and they lead towards measurable results and they stress the data approach. The projects take on average from a few months (Goh, 2002; Chiarini, 2012) to one year and thus their yield is short- and medium-term based. However, Six Sigma starts from a business plan and is deployed into the organisation as a whole. Like many other management systems, this means that Six Sigma passes through a long-term cultural change programme that is continuous as required by excellence.

3.3.3.8 The eighth assumption: involvement of the employees. Team oriented and use of certified Black and Green Belts

Management commitment and involvement is a fundamental pillar, especially concerning top and senior management. In any case, the entire organisation must be involved including 'white collars' and 'blue collars'. Six Sigma teams led by a Black Belt and some Green Belts need worker participation as well. Linderman *et al.* (2003) state that Six Sigma organisations should train all the employees by extensive programmes. Six Sigma needs important tools such as team building and team efforts and each Six Sigma team leader (i.e. Black and Green Belt) is supposed to be trained on these subjects (Lewis, 2006) not only on statistics matters. Black and Green Belts, in any case, should be certified through a precise and well-coded training (Harry and Schroeder, 2000).

3.3.3.9 The ninth assumption: Six Sigma requires skills based on statistics and data

Talking about statistics training, Hahn *et al.* (2000) referred to a 'democratisation of statistics' within Six Sigma. Every employee should be trained, at the requested level for his/her role, on statistics and quality tools. Six Sigma programmes have to balance between the cultural and technical skills

(Eckes, 2001) of every worker. Six Sigma is a well-synchronised clockwork in which everything is measured.

Six Sigma also has a strong approach based on facts and data. All the project results are validated using 'sigma level' around the target (see Table 2.1). It is expected that each Six Sigma project deliver either a measurable saving or a COPQ reduction. In several companies, the finance department is assigned to calculate and report these savings to the senior management. Hahn *et al.* (2000) are convinced that the disciplined, data-driven approach is the foundation of Six Sigma.

3.3.3.10 The tenth assumption: self-empowerment and responsibility

Although Six Sigma is based on strict rules such as the DMAIC pattern and Black and Green Belts certification, employees within the teams should act their roles with self-empowerment and responsibility. McAdam *et al.* (2006) stated that employees inside Six Sigma teams sometimes find themselves dependent on statistical knowledge and there is a lack of empowerment. Therefore managers should select the best employees for projects (Brue, 2002) basing the selection on the employees' abilities to bring to a close the assigned tasks. Each participant within Six Sigma projects is controlled by a Black or Green Belt but participants are supposed to take on responsibility about rules and scheduling.

As previously discussed Six Sigma is not the only management system that leads to Business Excellence and can be analysed within the so-called 'New Wave Management'. In the next sections Six Sigma will be compared with other similar systems such as TQM, BPR and Lean.

3.4 TQM

TQM is surely the oldest system and its roots sink into the first statistical works on product quality control carried out by Shewart (1939). These principles were further developed in Japan starting from the end of the Second World War. In the 1950s and 1960s the Japanese Government invited the American experts Deming, Juran and Feigenbaum (Aguayo, 1991) to outline new quality principles and management systems. Feigenbaum developed Total Quality Control (TQC) defining it as (1961, p. 6):

> *A network of management/control and procedure that is required to produce and deliver a product with a specific quality standard.*

It can be noted how TQC was focused on standards and specifications compliance, from the engineering department to shipping. The entire organisation through the use of procedures, work instructions and quality manuals aims to reach above all effectiveness for the customer (Ishikawa, 1985). In order to obtain efficiency as well, in two specific chapters Feigenbaum dealt with quality costs and statistical tools but the focus remains on effectiveness. Quality control was in this way an evolution of quality assurance (Kanji and Yui, 1997) and it began in the 1980s with the first issue of ISO 9000 standards.

According to Price (1989), TQC does not deal in detail with concepts such as empowerment, teamwork and supply chain management. In addition, there is not a clear path for TQC improvement projects and it seems that TQC is a sort of mechanic organisation in which everyone is supposed to follow procedures and instructions to do 'the right thing the first time' (Kathawala, 1989; Pasmore and Tolchinsky, 1989; Sitkin *et al.*, 1994).

TQC in Japan evolved into Ishikawa's (1968) Company Wide Quality Control that led TQC towards TQM. Ishikawa discussed how the different parts of a company should work together and changed the focus of attention from controlling to managing. From a review of quality management literature it is quite impossible to find who for the first time coined the phrase Total Quality Management. According to several authors (Grant *et al.*, 1994; Milakovich, 1991; Ehigie and Akpan, 2004) Deming was the founder of TQM, tweaking it in Japan and launching it in the world through the book *Out of the Crisis* (1986). There is a huge quantity of literature about TQM but, according to Knights and

Willmott (2000), sometimes authors contradict each other and nowadays it is unclear what TQM contains. Paton (1994) defined TQM as a philosophy not a science and as such it cannot be developed through a precise roadmap or pattern. A review of books for consultants and practitioners (Cali, 1992; Saylor, 1992; Pike and Barns, 1993; Ross, 1993; Zairi *et al.*, 1994; Hodgetts, 1995; George and Weimerskirch, 1998; Evans, 2004; Omachonu and Ross, 2004) shows that many improvement projects have been carried out under the TQM 'umbrella' but without a similar pattern.

3.4.1 Six Sigma and TQM at a first glance

Comparing Six Sigma and TQM by the three dimensions, the literature shows confusion in the management style and its strategies. An interesting paper by Chatterjee and Yilmaz (1993, p. 16) points out how TQM gurus such as Deming, Juran and Crosby did not agree on quality strategies:

> *...Deming is strongly opposed to management by objectives...Crosby recommended zero defects as a quality objective...Juran and Deming are against this because the inherent variability in all processes...*

Regardless, senior managers should be very involved and the most important crucial factor for TQM implementation seems to be management behaviour (Porter and Parker, 1993). A steering committee of senior managers normally leads the implementation program (Hill, 1991).

TQM focuses on quality performances, such as COPQ, although there are in the literature cases of integration between TQM and Corporate Social Responsibility (McAdam and Leonard, 2003; Zink, 2007; Meehan et al., 2006), and TQM and environmental aspects (Kitazawa and Sarkis, 2000; Daily and Huang, 2001; Miles and Russell, 1997). However, when comparing TQM and Six Sigma the approach is different. TQM tries to integrate its own model with the other models and mixes different patterns and tools whereas Six Sigma uses DMAIC and its tools for all subjects. The improvement within the processes follows the same goal: reducing variability around the targets and eliminating the root causes of defectiveness. However, Six Sigma complies with the DMAIC path and strictly follows rules in using tools and validating results. TQM does not offer a similar pattern, even though Japanese experts reinvented Deming's PDCA approach (1993) within a structure method called 'A3 report' (Ghosh and Sobek, 2002; Mazur *et al.*, 2008). Deming's PDCA can surely be considered the most common framework inside TQM (Luebbe and Snavely, 1997).

In dealing with human resources TQM stresses the use of team building and team efforts (Coate, 1993; Furey, 1993; Puffer and McCarthy, 1996; O'Connor, 1997; Bubshait and Farooq, 1999; Klefsjo *et al.*, 2001) as does Six Sigma, and employees' involvement is almost mandatory. Six Sigma demands precise roles such as Black and Green Belts and a particular certification for them. During the 1980s, TQM implementation at the bottom level was carried out through 'quality circles'. These latter were a risk-free way to begin (Lawler and Mohrman, 1985), especially to move the organisation towards an intense participative culture. Unfortunately, quality circles failed in many companies as described by Hayward *et al.* (1985), Hill (1991), Drago (1988), Gmelch and Miskin (1985) and Goldstein (1985). The reasons lie, first, in a weak senior manager's leadership, secondly in a non-participative approach and once more in a not clear connection with company strategies. By contrast, Six sigma deploys strategic objectives into CTQs (Harry and Schroeder, 2000) that teams are supposed to improve during the projects.

3.5 BPR

BPR is a system largely used during the 1990s. It leads to a deep redesign of business processes and it originated from Information Technology (IT) researches conducted by the Massachusetts Institute of Technology. Hammer and Champy can be considered 'the parents' of BPR and they wrote an article (Hammer, 1990) and a book (Hammer and Champy, 1993) in which they developed the first complete pattern to implement BPR.

Reviewing BPR literature, Knights and Willmott (2000) wrote a book in which can be found traces of BPR epistemological assumptions. The authors dealt with some BPR 'dimensions' that can be taken into account and compared with the three Six Sigma dimensions proposed in Table 3.1. According to Knights and Willmott, BPR improves cost, quality, service, speed and organisational transformation around processes. The approach to change is very fast and can be considered 'revolutionary'. Senior management should act a style of leadership that is aggressive and autocratic and employees become important only at a later stage. Consequently BPR is more top-down than Six sigma, TQM and Lean Thinking. In the process dimension, it can be added that, like Six Sigma, BPR is focused on the Voice of the Customer (Hammer and Champy, 1993) and its capture. In addition, BPR is 'IT-minded': the reengineering cannot be carried out without using computers, software and databases. Epistemologically, the way of implementing BPR into the processes is underpinned by a well-structured pattern.

Muthu *et al.* (1999) tried to summarise the BPR approach; they produced a sum of BPR methodologies described in literature and introduced five interesting steps:

- preparing for BPR;
- map and analyse As-Is process;
- design To-Be process;
- implementing reengineered processes;
- improving continuously.

Human resources involvement is important as well as teamwork, empowerment and responsibility. According to Hammer and Champy (1993, p. 70):

> *People working in a reengineered process are, of necessity, empowered. As process team workers they are both permitted and required to think, interact, use judgement, and make decisions.*

Limerick and Cunnington (1995) also argued that the strength of BPR lies in the empowerment of the individual. However, redistribution of responsibilities is an inevitable outcome of process reengineering (Davenport, 1993) and this could lead to a 'hypermodern neoauthoritarianism' as Willmott suggested (1993, p. 541). Knights and Willmott (2000), as already seen, claimed that BPR is a mainly top-down implementation and that employees are not important in the early stage.

According to Hammer and Champy (1993) and Bradley (1994) similar to Six Sigma there are precise players such as:

- a steering committee;
- the czar, that ensures resources and knowledge for the projects;
- project leaders;
- process owners;
- reengineering teams.

Thyagarajan and Khatibi (2004, p. 58) tried to summarise the assumptions discussed by depicting reengineering as having seven important areas:

- *Emphasize customer satisfaction.*
- *Use performance improvement programs and problem solving techniques.*
- *Focus on business processes.*
- *Use teams and teamwork.*
- *Bring about changes in values and beliefs.*
- *Work to drive decision making down to lower levels in the organisation.*
- *Require senior level commitment and change management for success.*

According to Kettinger *et al.* (1997), BPR techniques and tools are strongly based on mapping, benchmarking and IT. Just a few Six Sigma DMAIC tools such as project-management, brainstorming, cause-effects diagrams and problem solving are used within BPR projects (Klein, 1994; Kettinger et *al.*, 1997).

3.6 Lean Thinking

In the past decade Six Sigma has encountered Lean Thinking or Lean Productions, and shaped what George (2002) called Lean Six Sigma. What are the reasons for the fusion of the two most important excellence systems? First, it is important to understand what 'Lean Thinking' is and what the roots of this system are.

Taiichi Ohno, past Toyota Production manager, invented the 'Toyota Production System' and identified seven types of manufacturing wastes (Ohno, 1988):

- overproduction;
- inventory;
- extra processing steps;
- motion;
- defects;
- waiting;
- transportation.

These wastes increase process lead time and reduce value added for the customers.

Since the 1970s, competition has increased on factors such as zero defects, on-time delivery, price and relevant customisation (Piercy and Morgan, 1997). This scenario is the opposite of 'Mass production' (Shingo, 1987), in which there is a huge demand for products and services and the products and services are manufactured with low-cost resources and with poor personalization and quality.

Lean Thinking is a name derived from the book *The Machine That Changed the World: The Story of Lean Production* (Womack *et al.*, 1990). This book describes the movement of automotive manufacturing from mass production to lean production.

In order to implement Lean Thinking an organisation has to follow a simple theoretical path (Womack and Jones, 2008):

- Train Lean specialists and raise awareness about wastes inside the processes.
- Determine the sequence of activities within the processes using tools such as VSM and Makigami.
- Eliminate activities that do not add value to the process, and design the future state of the process.
- Improve the process (start over) through agile and quick teams that remove the waste just when it happens.
- Use of standardised Lean tools.

In general, the shorter the process is, the leaner the organisation and consequently the fewer the wastes (Sugimori *et al.*, 1977). Thus Lean Thinking is focused on the extreme simplification of the 'mainstream' with the intention of avoiding any kind of waste. To achieve these goals, Toyota Production System, or Lean Thinking, uses very specific tools such as 5S, Kanban, Heijunka, SMED and many others (Shingo, 1989; Ohno, 1988) invented by Toyota and other Japanese companies.

According to Womack and Jones (2008), agile and quick teams continually try to remove wastes and there is no pattern as rigorous as Six Sigma DMAIC for improvement projects. Through a review of practitioner literature or by directly analysing some case studies it can be found that teams usually manage 'Kaizen events' or 'Kaizen weeks' (Robertson *et al.*, 1992; Alukal and Manos, 2006; Manos, 2007; Dickson *et al.*, 2009), where Kaizen is the Japanese translation of continuous improvement (Imai, 1986). A peculiarity of these improvement projects is the short duration (on average a week) and the maximum involvement of people (Wickens, 1993; Liker and Meier, 2007). Lean does not need advanced statistical training, nor certified Black and Green Belts. Lean specialists are rather a team leader and Lean tools that are easy for everyone to use. Self-empowerment and responsibility are as important as in Six Sigma, as well as team building and team efforts. The tools derived from a typical manufacturing approach, indeed the 'Lean fathers' such as Ohno, Shingo and Monden, originally dealt with production processes inside Japanese companies.

There is no trace in academic literature of the application of Lean tools in engineering departments. Companies prefer tools derived from Six Sigma that are specialised for engineering and design that are provided by the so-called Design for Six Sigma (Mader, 2002; Coronado and Antony, 2002; Yang and El-Haik, 2009). More recently Lean has been applied in Health Care, utilities, finance and in the service industry in general (George, 2003; Ahlstrom, 2004).

3.6.1 A quick overview of Lean tools

Lean introduces simple but very powerful tools to reduce and banish wastes (Womack, and Jones, 2000). This section describes the general tools that can affect manufacturing and service industries, including Health Care. This overview is quite important in order to better understand their use in Health Care along with Six Sigma. The original tools derived from the Toyota Production System and their aims are summarised in the subsections below.

3.6.1.1 VSM (Value Stream Mapping)

VSM is the first tool used within the processes. VSM maps material flows and information flows that control the material. This visual representation boosts the process of Lean implementation by helping to identify the value adding and non-value adding activities (Rother and Shook, 1993). VSM is made up of two maps: the Current State and the Future State Map. VSM is typically used inside the Measure and Analyse stages of the DMAIC.

3.6.1.2 Makigami

The second tool for mapping the process is the Makigami. The Makigami is oriented towards transactional processes and it is derived from BPR tools (Hammer and Champy, 2003). There are no academic papers on this topic and practitioners and consultants have been implementing the tools under several names. Martin and Osterling (2007), for instance, introduce Metric-Based Process Mapping: a process-level mapping tool that helps to make effective and data-based decisions concerning waste reduction. It is used especially in the service industry including Health Care.

3.6.1.3 5S

Another important tool used in Lean Thinking is the 5S system. It improves order and cleanliness. The idea is that a messy workplace, desk, or area makes it hard to find things, easier to get distracted, and can introduce accidents, mistakes and lower productivity. 5S is structured by 5 important activities: separating staff, setting in order, shining, standardising and sustaining. In the health care order and cleanliness usually mean sanitation.

3.6.1.4 Quick Changeover

Using the one-piece-flow tool, it becomes fundamental to change quickly from one product or service to another. The doctor, for example, has to quickly change from one medical device to another that is necessary for a new patient. Quick changeover, also known in the manufacturing field as SMED, is a particular tool that avoids dead times and improves changeover operations.

3.6.1.5 Other Lean Thinking tools

There are quite a few tools derived from Lean Thinking and potentially used in a Six Sigma model. This thesis is dedicated to Six Sigma in the Health Care sector; therefore the most important tools for Health Care have been taken into account. Nonetheless, Table 3.2 summarises Lean Thinking tools and their use inside manufacturing and the service industry.

Table 3.2: Lean Thinking tools and their use

Lean Thinking tool	**Scope of the tool**
VSM (Value Stream Mapping)	Mapping the flow of the product or service for seeking wastes
Makigami	Mapping the flow of a service. Particularly used in the Lean Office and for transactional processes. Used for finding non-value added activities
5S	Five very simple steps for setting in order and cleaning up the workspace
One-Piece-Flow	Processing different products and services one at a time avoiding lots and WIP
SMED – Quick Changeover	It reduces the set-up times for machines, plants and organisational

	systems
Kanban	A specific card that signals the need of a product or a service. It levels off the flow reducing the WIP and introducing the so-called just-in-time
Total Productive Maintenance (TPM)	A system for introducing preventive maintenance of machines and equipment and raising the awareness of the workers about self-maintenance
Poka-yoke, mistake proofing	A tool for avoiding human errors on the processes, reducing defects

3.7 Comparing Six Sigma with TQM, BPR and Lean Thinking and integration discussion

After reviewing the literature and analysing the findings, Six Sigma, TQM, BPR and Lean Thinking can be compared through the ten epistemological Six Sigma assumptions. The results have been summarised in Table 3.3. Following the history of the four systems, in the 1980s many companies introduced firstly just TQM, then BPR was set out in the 1990s and in the past ten years companies have been implementing Lean and Six Sigma at the same time. According to the literature review results, some authors consider that TQM is more a philosophy than a science (Patton, 2004). This means that TQM is sometimes implemented without a precise roadmap or pattern. Looking at Table 3.3, TQM for instance does not have a precise pattern such as DMAIC for improvement projects. Deming's PDCA is another sort of philosophy, not a methodology and, more important, many TQM tools have been inherited by Six Sigma. Several managers declare that TQM is no longer applied because from the ashes of TQM Six Sigma was born. This latter point of view agrees with one of the authors as shown in the previous sections. BPR also seems to be less used by companies. According to the literature review, BPR was popular during the 1990s basically because companies needed to downsize and apply IT better. Analysis of BPR assumptions (see Table 3.3) shows how, downsizing apart, the system is by nature 'aggressive', fast and technological minded. In addition, without taking into consideration IT tools, BPR teams use mainly mapping and problem-solving tools. Nowadays, the use of IT to support business operations is no longer considered a breakthrough but just a tool. Reengineering projects can be easily carried out through Six Sigma DMAIC and its complete tools.

Lean Thinking or Lean Production would have met Six Sigma sooner or later; the reasons are well known and have been discussed in the literature since 2002. As Table 3.3 shows, Six Sigma is problem focused and it assumes that process variation is waste because it generates defects and COPQ. Lean Thinking, by contrast, is focused on process flow and lead time and views any activity that does not add value as waste. Lean Six Sigma combines the 'speed' introduced by Lean, the management of improvement projects, the Six Sigma DMAIC pattern and the Six Sigma capability of reducing variation. Lean Six Sigma seems to be a well-established model for business excellence as confirmed by several authors (Arnheiter and Maleyeff, 2005; Kumar *et al.*, 2006; Wedgwood, 2006). Lean Six Sigma, in a nutshell, is the linking of different tools by the DMAIC pattern that aims to reduce waste and COPQ. Lean Thinking and Six Sigma require a visionary leader, are based on involvement of employees, are team oriented and involve long-term cultural change. The DMAIC rigour could be slightly adapted to the speed of 'Kaizen team' and skills enlarged by Toyota Production System tools. But why has only the join between Lean and Six Sigma produced such a new system?

As previously discussed, TQM and BPR did not bring anything of novelty within Six Sigma and, in a sense, in the end they would have been absorbed by Six Sigma. By contrast, Lean has surely lent tools to Six Sigma for speeding up the flow that Six Sigma did not have.

3.8 Conclusion of the discussion about integration

In this first part of the chapter Six Sigma has been analysed in a philosophical way. Ten epistemological assumptions, divided into three dimensions, have been found through a literature review. The ten Six Sigma epistemological assumptions have been used to compare Six Sigma with TQM, BPR and Lean

Thinking. The comparisons are summarised in Table3.3 and discussion about them comes to conclusions that are also important for the Health Care model inquiry. First, it seems that Six Sigma has absorbed TQM. Indeed, Six Sigma contains all the TQM tools and many others, and it offers a more structured and measurable pattern, the DMAIC, for improving processes. According to Patton (2004), TQM is more a philosophy and in the literature there are criticisms about typical goals that TQM can reach (Chatterjee and Yilmaz, 1993) and its organisation. BPR has been an important system used mainly to downsize organisations and introduce IT into the processes. Recession during the 1990s forced many companies towards this direction. Criticisms about BPR are that it is considered 'aggressive' and sometimes not completely people involving. Nowadays Six Sigma and Lean Thinking seem to offer the same tools for reengineering the processes. Literature over the past five years indicates that interest in BPR will diminish. Lastly, it seems that Six Sigma and Lean Thinking have made a good marriage, bringing a dowry of variation and lead time reduction in the processes.

Table 3.3: Epistemological comparison between Six Sigma, TQM, BPR and Lean Thinking

Ontological assumption: Business excellence and New-wave management

Way of implementing

Six Sigma assumption	TQM assumption	BPR assumption	Lean Thinking assumption
Improves business performance in general, cost reduction model particularly concerning COPQ	Improves quality performance, particularly COPQ	Improves business performance in general, cost reduction model, streamline and downsize oriented	Reduces wastes, cost reduction model, particularly increases value added
Requires visionary top management. High commitment and involvement	Requires top management. High commitment and involvement	Requires aggressive and autocratic top management. High commitment and involvement	Requires visionary top management. High commitment and involvement
Reduces variation within the processes. Certified results	Improvement of the processes in general	Reduces process hand-off, number of employees and organisational levels	Reduces process lead time
Requiring focus and capture of the voice of the customer	Requiring focus and capture of the voice of the customer	Requiring focus and capture of the voice of the customer	Requiring focus and capture of the voice of the customer
Focuses on improving processes of the whole organisation through DMAIC approach	Focuses on improving processes of the whole organisation through quality team without a precise pattern	Focuses on improving processes of the whole organisation through reengineering projects (there is not a precise pattern)	Focuses on mainly improving production processes through Kaizen team without a precise pattern
Uses of all kinds of tools derived from quality and other management systems	Uses the traditional quality management tools	Uses mapping tools, problem solving and all the tools provided by IT	Uses specific and well-coded tools invented in the Toyota Production System

Short- and medium-term improvement project but long-term cultural change	Short- and medium-term improvement project but long-term cultural change	Short- and medium-term improvement project, quick and ‘aggressive’ cultural change	Quick and intensive projects but long-term cultural change
Involvement of employees. Team oriented and use of certified Black and Green Belts	Involvement of employees. Team oriented	Involvement of employees. Team oriented with well-defined figures (Czar, projects leader, etc.) Sometimes employees are involved in a later stage	Large involvement of employees, especially workers. Team oriented
Requires also skills based on statistics and data	Requires skills based on quality management in general	Requires generic skills based on problem solving and IT	Requires skills based on Toyota Production System tools in general
Self-empowerment and responsibility	Self-empowerment and responsibility	Self-empowerment and responsibility. People sometimes are forced top-down	Self-empowerment and responsibility

3.9 Literature review for the model

The research has so far analysed the ways in which Six Sigma and other similar approaches have been discussed and defined in a general way. After having philosophically located Six Sigma and compared it with TQM, BPR and Lean Thinking, this section deals whit a specific review of Six Sigma literature. Indeed, reviewing literature the research will analyse how practitioners and academics have developed the manufacturing model and started discussing Six Sigma in the health care. The results of the review will be the first traces in order to understand what the differences from the manufacturing model are and if some authors have deeply investigated on Six Sigma applied to the health care.

3.10 Practitioners' perspective on Six Sigma

3.10.1 The first books concerning Six Sigma

The roadmap to define the Six Sigma organisational model started with Harry and Schroeder's (2000) important contribution. The authors, in practice, are the founders of the modern Six Sigma approach, and authors since then have arranged and enhanced Harry and Schroeder's theories. Their book *Six Sigma, the Breakthrough Strategy* is the 'bible' of Six Sigma and establishes the universally accepted DMAIC method. In the early chapters Harry and Schroeder argue that Six Sigma is a problem-solving venture and that, basically, the Six Sigma model is based on the launch of projects of continuous improvement managed through a specific path. This latter, in the early work of Harry, was divided into eight steps:

- R, to recognise problems;
- D, to define the boundary of the problem;
- M, to measure the capability and the CTQ;
- A, to analyse the data;
- I, to improve removal of root causes of variation;
- C, to control the results achieved and measure the capability;
- S, to standardise the methods and the processes;

- I, to integrate standard method into other processes.

Harry and Schroeder summarise the eight phases in the five now universally accepted phases of DMAIC and suggests this approach as more operative for organisations. In practice, the R phase is merged with the D, and the last three C, S and I are merged in the C phase. Subsequent authors adopt the five-phase DMAIC pattern. Although this pattern is surely the Six Sigma DNA, it can be considered an evolution of Deming's (1986) Plan-Do-Check-Act, and is more than a breakthrough.

The text of Harry and Schroeder also has the advantage that it does not enter into a debate about the merits of the tools that you use in the various stages; in this way it contributes to the delineation of Six Sigma as a management model of excellence that aims to reduce the costs of poor quality. Six Sigma is a framework within which managers can enter both statistical tools and management tools that are used to achieve results about costs and quality. The only new aspect is that from the text seems to emerge the suggestion, in a manner not entirely clear, that the success of Six Sigma projects in the Public Health Care sector can be measured without economic parameters.

Unlike other later texts (for instance Pyzdek, 2003, see Section 3.3) Harry and Schroeder focuse on the connection of Six Sigma projects within the various levels of the organisation (business, operations, process) not forcing the use of SPC, DOE, Taguchi and other tools into manufacturing reality. Harry recognises the important use of statistics, particularly in the analysis. Finally, a crucial aspect of Harry and Schroeder's text is the definition of the players involved, especially Champion, Master Black Belt, Black and Green Belts. In one specific chapter entitled "The Six Sigma Players" the roles of these figures are defined for the first time, their responsibilities are compared and, above all, paths for training in the role are highlighted. For example, to become Black Belts, who are the most important figures because they are project team leaders, Harry states that managers have to attend a four-week course distributed across four months; no detailed justification is, however, given on the choice of such a training path.

Harry and Schroeder's book also addresses the application of Six Sigma in the service industry, including Health Care, in a dedicated chapter. The chapter is not so complete as others and it confuses processes in the service industry, public sector and manufacturing such as sales, administrative and others; in addition, there is no comparison with the manufacturing field. The chapter seems to argue that there is no particular difference among sectors; however, in citing the case of a hotel, it is stressed, in a generic way, that some Six Sigma projects were managed through mapping tools and Pareto Analysis and without advanced statistics. Instead the chapter introduces the important concept of 'transaction'. In calculating the number of defect opportunities, Harry claims that *we substitute the word transaction for the traditional notion of manufacturing parts*. The book of Harry and Schroeder, in the last analysis, with the limits mentioned above, has laid the foundations for the subsequent literature on Six Sigma, both in the manufacturing and service industry.

Pyzdek (2003) penned a fundamental book, especially from an operational point of view. The text, in fact, completes, in some ways, the lack of precise references to the tools in Harry's text. Pyzdek associates quality and statistical tools (i.e. Quality Function Deployment, Kano Analysis, FMEA, SPC, DOE etc.) with each phase of DMAIC, thus providing the reader with the possibility of application in the company. The text does not have, therefore, an academic connotation and there are no deep analyses, however, it does describe specific applications in the service industry and the Public Sector. Cases of manufacturing and Public Administration are treated equally, without underlining the peculiarities and, of course, without outlining a model for Health Care.

3.10.2 Review of other practitioners' point of view

Several other texts were published in the period between Harry and Schroeder's (2000) book and Pyzdek's (2003) book but they typically follow a general approach to Six Sigma without identifying the differences among the service industry, Public Sector and manufacturing. Among these texts can be quoted *Six Sigma for Managers* (Brue, 2002), in which, in summary, the DMAIC path established by Harry is taken and outlined, and the advantages obtained in the management of Six Sigma are described. The paragraphs dedicated to

'Case studies' identify various cases of Six Sigma application in different areas: a company that counts a large government agency as one of its customers, a typical manufacturing company and a particular case of accounting for delinquent accounts. The paragraphs, however, do not highlight, once again, the differences among services and manufacturing and Health Care.

The most complete and innovative book about transactional Six Sigma is probably *Lean Six Sigma for Service*; George's (2002) book mixes Lean Thinking with Six Sigma in a very innovative way. The positive aspects of this book are the following. Firstly, the attempt to enrich Six Sigma with other instruments from the so-called Lean Thinking (Womack, 2000) admitting, in this way, that the traditional instruments of Six Sigma for manufacturing need, at least, to be integrated. Secondly, the first attempt, in the history of literature on Six Sigma, to distinguish between improvement projects about Six Sigma and improvement projects relating to Lean Thinking. The division, according to George, would be given by the speed. In the text, in fact, Six Sigma projects are more concerned with quality, whereas Lean projects reduce processing times. Thirdly, is the use of the DMAIC framework in which to insert instruments typical of Lean. In this way George exceeds the previous literature that considered only typical tools from TQM and statistics as suitable for Six Sigma. George, in the text, gives, in fact, examples of DMAIC and concurrent use of Lean tools such as Value Stream Mapping (VSM), 5S, Single-Minute Exchange of Die (SMED) and so on. However, George forced the typically manufacturing approach with Lean tools into service processes. For example, customers waiting in line to be served become the manufacturing Work In Process (WIP) or the refurbishment of an office becomes the set up of a plant. Nevertheless, a specific model for services or rather for Health Care is not outlined in the book.

George (2003) tries to overcome the limits mentioned above in a later book that displays typical cases of the Public Sector. The text in question, *Lean Six Sigma for Service*, is still the most complete and comprehensive in terms of defining of a model for services and the Public Sector. Starting from the ideas expressed in the text of 2002, in particular the inclusion of Lean tools in DMAIC, George sets out new and important principles, in particular:

- Six Sigma requires other instruments, arising for example from Lean, mainly, according to George, because Six Sigma focuses on reducing process variability and, when this is not possible, on redesign through the techniques of Design For Six Sigma (Mader, 2002). However, the reduction in variability and the redesign process are based mainly on statistical tools that are not suitable for everyone.
- The Six Sigma tools do not particularly affect the reduction of activity without value added.
- The Six Sigma tools do not impact on increasing the speed of activities and the speed of response.
- Six Sigma projects, following the DMAIC pattern, are not so quick at problem solving such as the Lean Kaizen Workshop; often, in fact, the problems require immediate and fast resolution.

The important aspect of this text, ultimately, would exceed the concept of using only instruments arising from statistics or TQM; Six Sigma can coexist with other operating tools such as those of Lean Thinking, editing, in this way, the skills of teams dedicated to the projects. However, George's purpose was to demonstrate the point of convergence between Lean Thinking and Six Sigma, by highlighting the strengths and weaknesses of both and synergies. The text, however, even if it takes a significant step forward compared to previous literature, does not paint an accurate model for Public Services in the sense discussed in the previous chapters.

In 2004, Akpolat wrote a specific book in order to discuss Six Sigma and service environments. The title of the book is *Six Sigma in Transactional and Service Environments* and it is divided in two parts: the first part provides the knowledge for understanding Six Sigma methodology and its underlying concepts; the second part consists of practical examples of Six Sigma application in the service sector, including Health Care. In the first three chapters the author shows the foundations and benefits of Six Sigma and points out principles already known in the previous literature such as 'the voice of the customers', mapping the processes, the DMAIC stages and so on. The differences between manufacturing and service are only discussed in a theoretical way, without any kind of consideration of the possibility of shaping a service or Public Sector model. The second part of the book presents and discusses five case studies; the most interesting one seems to be the 'Queensland Rail, Australia' (Akpolat, 2004), in particular concerning Master Black Belt, Black and Green Belt training. The subject is not so developed in the chapter but the author points out that the selection of the Belts is based on the capability to fulfil the organisation's targets, rather than technical and statistical skills. This could be an interesting new point of view not debated by other authors but, unfortunately, not studied in detail by Akpolat (2004).

Yang (2005) penned a book called *Design for Six Sigma for Service*, in which he pointed out the concept of 'transactional Six Sigma' and of operational methods, but again he used a typically manufacturing approach and, in the cases analysed, he incorporates many of the concepts already established by George and Harry. Snee and Hoerl (2005) wrote a book called *Six Sigma Beyond the Factory Floor*. In 2005, the book seemed to be a breakthrough in the field of Six Sigma for services: W.R. Grace's CEO, Mr Norris, wrote in the book's front page this comment:

> *...the book dispels the myth that Six Sigma is limited to the manufacturing process by providing compelling examples of transactional successes combined with a guide to practical deployment...*

Indeed the author in the second chapter argues that Six Sigma has not been deployed holistically and introduces an important paragraph dedicated to the differences between manufacturing and service sectors. The paragraph shows that there are conceptual differences (e.g. lack of tangible output of product) and technical differences (e.g. lack of engineers). The technical differences should lead to a different training for the Black and Green Belts: a different way to teach statistical tools and integration with tools more 'Lean oriented' such as process diagrams, value stream and flowcharts. The authors declare that "*...the level of statistical rigor needed is less than that needed in manufacturing...*" but, contradicting themselves, they also write that "*...for Master and Black Belts, however, solid technical and statistical skills are needed...*" The authors even suggest the hiring of external technicians dedicated to particular Six Sigma projects in which the use of statistical tools is prevalent, however, normally this is not easily done, especially in the European Public Sector.

Finally it can be claimed that the practitioners have not yet a specific model for the public health care. The authors bring the conclusions to a holistic not clear model for both the sectors, forcing manufacturing principles into Public Administration. Interesting suggestions about the possibility of using Lean tools within the DMAIC pattern come up. Statistical tools seem not be under discussion, even if this is a reasoning mainly linked to manufacturing processes.

3.11 Review of academic articles

3.11.1 Review of generic academic articles on Six Sigma

Several articles were issued from 2004 to 2010 concerning the state of the art of Six Sigma in services and manufacturing industries, in particular in the peer-reviewed magazines. In this section only the most significant papers for the scope of the thesis have been reviewed.

Szeto and Tsang (2005) wrote about the critical factors that will make Six Sigma projects successful in organisations. The paper is based on a literature review and its conclusions demonstrate that Six Sigma is a model in which the most important assumptions are: management involvement and commitment, linking Six Sigma to business strategy, change of organisational culture, organisation infrastructure, training, tools applications, linking Six Sigma to stakeholders, project selection, prioritisation and management of the projects. However, these assumptions are generic and could be found in each management system including TQM, BPR and Lean Thinking.

Dahlgaard and Dahlgaard-Park (2006) tries to analyse Six Sigma, Lean Manufacturing and TQM, concluding that Six Sigma has to focus more on understanding the human factor rather than the tools, the training and the techniques.

Pestorius (2007) wrote about transactional Six Sigma. In his view, Six Sigma is at present more focused on transactional processes, without differentiating between manufacturing and services. As a result, sales and marketing, for example, are managed like financial or health care services.

De Mast and Bisgaard (2007) analysed the DMAIC pattern and the use of statistical tools within the pattern. The conclusions of the article are that Six Sigma uses a scientific approach rather than a practical one and the DMAIC pattern is fundamental and axiomatic. However, this result contradicts the authors who claim that Six Sigma is a very practical model.

Al-Shaghana and Davison (2007) wrote a paper in which they investigate in an empirical way the influence of Six Sigma on quality culture. The results show distinctly how companies that are using Six Sigma have more deep-seated quality values such as commitment, awareness, training, participation and performance evaluations.

Wurtzel (2008) led research about the reasons for the failure of Six Sigma implementations and one of those reasons seems to be the lack of a model. Thus in 2008 both manufacturing and Public Health Care industries claimed this important lack.

Moullin (2008) claimed that Six Sigma, as well as Lean, cannot be applied to the UK public health care sector in the same way as it is applied in manufacturing. The author analysed how the needs and requirements of patients in health care differ from patient to patient whereas manufacturing product requirements have much more repeatability.

Schroeder *et al.* (2008) tried to shape a model; the model is a programme structured in five steps. The first is to involve the management: senior management has to select the team, identify the strategic projects and support Six Sigma implementation. The second step is to train specialists (e.g. Black Belt or Green Belt). Third, to establish metrics and measurements based on cost, quality and times; fourth, to follow the DMAIC path in a systematic way and fifth, to select and prioritise the improvement projects. At the end the so called model is more a programme to implement Six Sigma and the features of such a programme can be found in Harry and Schroeder's book (2000).

Chakravorty (2009) wrote an interesting article about a general model to implement Six Sigma. He recognises that such a model is still lacking and there is increasing concern about implementation failures. In this article, Chakravorty, through a successful Six Sigma programme in a network technology company, tries to establish a model. Aware of the well-known limitation of a similar case study approach, Chakravorty shapes a six-step implementation programme. According to Chakravorty (2009, p. 1):

> *...The first step is to perform strategic analysis driven by the market and the customer. The second step is to establish a high-level, cross-functional team to drive the improvement initiative. The third step is to identify overall improvement tools. The fourth step is to perform high-level process mapping and to prioritize improvement opportunities. The fifth step is to develop a detailed plan for low-level improvement teams, and the sixth step is to implement, document, and revise as needed...*

The six steps could represent a precise programme for Six Sigma implementation but they are based on a network technology company and the means to generalise the model are not taken in account. It is not claimed that the model is general or that it could be implemented for example in the Public Health Care industries.

Since 2004 many other authors have debated the important factors for a successful implementation of Six Sigma. Skills of the participants in the projects, management commitment, involvement, review and awareness of the staff are the important Six Sigma factors quoted by McAdam and Evans (2004), Gijo and Rao (2005), Ladani *et al.* (2006), Savolainen and Haikonen (2007) and Zu *et al.* (2008). Other authors focused on the technical and managerial skills for Black Belts. For example Antony *et al.* (2007) pointed out the need for the full-time involvement of the Black Belts and the intense training on statistical tools. Foster (2007) argued that technical and managerial skills are fundamental to the success of Six Sigma implementation and that the skills can change depending on the sector.

In conclusion, the review of generic academic articles shows how there is no trace of a specific model for Six Sigma in the health care. The model is rather a programme to implement it. In addition, the authors do not agree with each other about the importance of different factors such as tools, training and cultural changes.

3.11.2 Review of academic articles on Six Sigma for Health Care

The academic literature on Six Sigma for Health Care is less profuse than the other sectors. There are many articles about the specific application of Six Sigma tools, especially statistical tools used in departments, laboratories and hospital wards. However, there is a complete lack of discussion or attempts regarding the development of a model for Public Health Care in both Europe and USA. The following are some interesting articles that contribute to the debate.

Starting from 1998, Chassin (1998) analysed why health care should embrace Six Sigma, concluding that is important for reducing defect rate and improving processes. The author outlined how at that time health care was thinking of implementing Six Sigma.

Ettinger (2001) discussed about the application of Six Sigma inside a New Jersey health system. The conclusions are that the manufacturing approach could be suitable for this specific American health system as well.

Sehwail and DeYong (2003), analysed several US case studies concluding that Six Sigma can lead to achieve benefits in terms of better efficiency, cost effectiveness and customer satisfaction. However the focus in this paper seems to be the efficiency and the reduction of the costs instead of patient satisfaction.

Volland (2005) wrote an article dedicated to Public Health Care and Six Sigma in which the focus of the results seems to be more in terms of satisfaction for patients, employees and doctors rather than the measure of standard deviation around a quality target. It seems that the use of statistical tools is less important than in the manufacturing sector.

A national survey was carried out by Feng and Manuel (2007) in the USA. The survey is about Six Sigma implementation in the US Health Care sector, and it determined that 54% of US Health Care does not intend to embrace Six Sigma. The reasons are not deeply investigated but it seems that Six Sigma programmes are expensive (Berg, 2006), manufacturing oriented and managed with difficulty.

Proudlove *et al.* (2008), wrote an interesting article about the implementation of Six Sigma inside the National Health System in the UK. The projects analysed by the authors and carried out in England show some difficulties. The authors underlined that not all the manufacturing principles can be applied in the health care. However there is not an analysis of such differences.

In conclusion there is a complete lack of discussion or attempts regarding the development of a model for Public Health, enlightening what the differences are from the manufacturing sector. In any case patient satisfaction is considered as important as economic issues. The articles are mainly focused on case studies inside delimited parts of health organisations such as laboratories or single departments, especially in the US. Somehow few authors have started analysing the difficulties of implementing Six Sigma inside public health care sector.

3.11.3 Review of articles on organisational climate within Public Health Care

As shown in the first chapter, the European Public Health Care Sector has a way of management that differs from the Private Health Care sector and the US Public Health Care sector. These differences are not only based on financial and economic matters. Role conflict and job satisfaction within improvement teams are particularly important for successfully reaching targets in European Public Health Care (Parker and Bradley, 2000). Even if there is a lack concerning psychological aspects inside Six Sigma-European Public Health

Care teams, it could be interesting to review articles about organisational climate in this sector. Piko (2006), for example, studied the relationship among burnout, role conflict and job satisfaction in a Hungarian hospital. Piko found that role conflict was a factor contributing positively to emotional exhaustion and consequently to team efforts. In some European countries where politics strongly affect the decision making inside Public Health Care, such as Italy and France, some authors have written about conflicts between top managers. Kob and Finzi (2008), for example, analysed the roles of the Head of a Department and the Head of the Hospital inside Italian and European Public Health Care. They show that there are conflicts between the two kinds of top managers and point out that in Italy the Hospital Director sometimes is a sort of politician instead of a real health care expert. Last but not least, several authors investigated the conflicts between doctors and paramedics, especially about patient care roles (Hojat *et al.,* 2003; Dougherty and Larson, 2005). Brolis *et al.* (2006) in an Italian paper wrote an analysis of the reasons that do not permit doctors and nurses to work as well as they can together. In this article the authors explained how cross-functional training about teamwork is important in all Public Health Care processes. Doctors and paramedics are not used to training about team building and team efforts.

3.12 Conclusions

The review of Six Sigma literature has highlighted how, through a journey that began in 2000 with Harry and Schroeder's text the various authors have established the model for the manufacturing field. Through the results of the literature review it can be claimed that for Health Care:

1) The classic Six Sigma tools may not be sufficient or fit, therefore Six Sigma is borrowing instruments from other contexts, such as Lean Thinking and TQM.
2) Some authors have underlined the importance of achieving strategic goals such as patient satisfaction instead of pure economic goals.
3) The skills within the Six Sigma teams could differ from the manufacturing ones.

4) There is no discussion about how and when to use advanced statistical tools in Health Care projects. For the most part, authors indicate that all the tools described in the second chapter can be applied in both sectors.

5) General organisational aspects such as roles and responsibilities, especially inside top management, and conflicts within Six Sigma teams are supposed to be investigated. This is particularly important in the European Public Health Care sector.

Finally it is interesting to notice how some Health Care industries consider Six Sigma not as easy to implement as other management systems. This could be understood as a request for a specific model that is different from the traditional manufacturing model that some authors try to force on Health Care. The literature has, however, not entered yet into the real specificity of European Public Health Care. Differences from the manufacturing model, possibility of managing in another way the DMAIC pattern, skills and training of the team and expected results are aspects, for example, marginally treated and, in any case, not included in a single model for Public Health Care or even in European Public Health Care. The first part of the chapter has highlighted, through another literature review, how the way of implementing Six Sigma in the manufacturing sector can be based on ten epistemological assumptions and Six Sigma can be classified into new-wave management along with TQM, BPR and Lean Thinking.

The next chapter will try to understand what could be the best methods to carry out the research for developing the model and bringing to light the differences from the manufacturing sector. The inputs for the research are the conclusions of this literature review, especially for the inductive reasoning and qualitative methods and for the grounded theory as well. The ten epistemological assumptions shown in Table 3.1 will be also taken into account for a discussion between manufacturing and European Public Health Care models. In particular, after the Health Care model and its theoretical principles have been shaped the research will try to understand the epistemological assumptions of the new model.

Chapter 4 – Research methodologies

4.1 Introduction

In the previous chapter it has been shown how the literature has not yet outlined a specific model for the European Public Health Care sector. Thus the literature needs new contributions to enrich previous works on Six Sigma. Ten epistemological assumptions for the manufacturing sector have been established through a deep literature review and through a comparison between Six Sigma and TQM, BPR and Lean Thinking. One of the most important steps of the research, according to Chapter 1, after stating general research questions and drawing the boundaries, is to collect relevant data in order to interpret them for the conceptual and theoretical work (Bryman, 2001).

This chapter attempts to explain the reasons why this research is underpinned in a deductive way but with a first stage of inductive reasoning. The chapter deals with the methods, either qualitative or quantitative, used to collect data from the European Public Health Care Sector for building the Six Sigma model. Last but not least, the chapter debates the merits of using both qualitative and quantitative methods in the so-called triangulation. Within these methodologies the use of grounded theory is also discussed, even if this latter is considered something separated and not related to a traditional inquiry that starts from a literature review. As discussed in section 4.6, grounded theory inside this research comes from a deductive perspective rather than an inductive and helps the researcher to better understand what to validate in the quantitative stage.

4.2 Deductive or inductive approach?

This research is mainly deductive; inductive reasoning is used in a first and more limited stage as described in the next sections.

Inductive reasoning (from the Latin *inductio*) is a logical process that builds theory (Heit, 2000). In particular, starting from specific cases, inductive logic tries to establish a general law (a theory) about the phenomenon under investigation. Deductive logic is a theory-validating process that starts with a stated theory or generalisation and tries to understand whether the theory fits specific cases or not (Johnson-Laird *et al.,* 1991). Thus it seems that these two ways of reasoning are diametrically opposite. On the one hand there is a hypothetic–deductive or positivist process and on the other a naturalistic or interpretative one. Indeed both of the processes are still under discussion and they have been enriching many debates.

The inductive process has received some criticism of which the most important was issued by Karl Popper (1959) in his famous book *The Logic of Scientific Discovery*. Popper argued that science should only approach a methodology based on falsification because there is not a sufficient number of cases that can ever prove a theory but a single experiment can contradict a scientific theory. Popper's thought modified positivist methodology and emphasises the importance of unbiased data collection (Johnson and Clark, 2006) in order to test hypotheses.

In management science, researchers frequently use deductive processes. However, some authors (Deshpande, 1983; Bonoma, 1985) argue that in management science the deductive approach in many cases is applied hastily. Management researchers should go through a deductive process after gaining a deep understanding of the concepts that operate in their research area. Deshpande (1983), for example, criticised marketing researchers for not being involved in theory generation; marketing science has historically confirmed theory rather than discovering a new one.

Simon *et al.* (1996) define various criticisms of the research methodologies traditionally carried out in quality management. Some of these criticisms are based on the lack of theorising and the use of deductive and quantitative methods to imply every aspect of the research.

Inductive and deductive reasoning have a very different 'feel' to them when someone is conducting research. Inductive reasoning, by its nature, is more open-ended and exploratory, especially at the beginning. Deductive reasoning is narrower in nature and is concerned with testing or confirming hypotheses. Even though a particular study may look like it is purely deductive (e.g. an experiment designed to test the hypothesised results of some factors on some outcome), most social research involves both inductive and deductive reasoning processes in the project. In fact, it should be understood that the two approaches could be assembled together into a 'single loop'. The researcher in this way can continually cycle from theories down to observations and back up again to theories. Even in the most scientific experiment, researchers may observe patterns in the data that lead them to develop new theories. A special methodology, the so-called grounded theory, enables the researcher to use the inductive and deductive approach at the same time (Glaser and Strauss, 1967) as better shown in Section 4.6. Sitter *et al.* (1997) stated that grounded theory uses abstract concepts to interpret and analyse a series of general phenomena but it is based on practical experience. According to Cohen *et al.* (2007), research can develop theory through different methods looking at the same event or process in different settings or situations.

As shown in Section 4.6, grounded theory has been used as a 'framework' to better understand connections among the hypotheses that have to be tested in the quantitative stage.

4.3 The structure of the research

The previous section described a single loop using an inductive–deductive approach. This research uses the single loop. In the first inductive stage, an interview with doctors who have a good knowledge of Six Sigma has been carried out. In order to better understand the culture and the organisation of European Public Health Care, a focus group and two observations have been carried out as well.

The observation represents an important part of the first stage because the researcher can directly observe how Six Sigma projects are implemented and conducted inside two European public hospitals, and also gather data and information about the organizational climate. It has been discussed in the literature review that inside European Public Health Care, climate, roles, responsibilities and even politics can make a difference when trying to reach improvement targets. In this way the research uses multiple methods inside the qualitative inquiry in order to capture as much of Six Sigma in the public health care as possible. This is typical of postpositivism tradition in the social sciences. According to Denzin and Lincoln (2003, p. 11):

> *Postpositivism relies on multiple methods as a way of capturing as much of reality as possible. At the same time, it emphasizes the discovery and verification of theories.*

Gathering and analysing the results of the interview, the focus group and the observation, the research through grounded theory generates theoretical principles transformed into hypotheses for a second deductive process. In this way grounded theory is carried out with a deductive approach in order to analyse connections among the hypotheses and whether or not they are suitable for the Health Care model.

The final validation is strictly tied to the Chi-square test as a quantitative method (Bryman and Cramer, 1990). Therefore the hypotheses are generated from the first inductive process, in particular using the above-mentioned qualitative methods and grounded theory. Grounded theory is also used to find connections and a 'story' within the hypotheses.

The mixing of methodologies, in this case an interview, a focus group, an observation and a Chi-square is a typical form of triangulation. Figure 4.1 shows the path of the research, the methodologies used, the scope and the outputs achieved.

According to Figure 4.1 the research path is based, in the first inductive/qualitative stage, on interviews concerning Six Sigma with two doctors in two different hospitals, a focus group and a case study carried out inside one of the two public hospitals. Therefore the scope of the fieldwork in the qualitative inquiry is not as wide as the survey used in the following quantitative stage. Indeed just a small sample of two hospitals have been investigated, on the contrary more than 500 people have answered to the questionnaire. In fact the large quantity of information and data gathered through the interviews, the focus group and the observation will be analysed just to issue concepts and theoretical categories. Qualitative methods can be used when understanding the cultural context from which people derive meaning is an important element of a study (Rossman and Wilson, 1994). Such cultural context is, usually, ignored in quantitative studies. According to Flyvbejerg (2006), a small sample can be utilised for generating new ideas and consequently hypotheses and that is particularly suitable in the first stage of a triangulation research. In any case the quantitative stage will strengthen the hypotheses derived from the few case studies. Indeed by the means of a chi-square test the hypotheses will be tested and finally validated.

The following subsections review the qualitative methods used within the inductive approach and they try to underline the strengths and weaknesses of the methods. The approach taken with quantitative methods is discussed in the sixth chapter.

4.3.1 The use of triangulation

A quantitative research methodology is appropriate where quantifiable measures of variables of interest are possible, where hypotheses can be formulated and tested, and inferences drawn from samples to populations (Orlikowsky and Baroudi, 1991).

Qualitative methods are appropriate when the phenomena under study are complex, are more sociological, and are not so simple to measure. Typically, qualitative methods are used when understanding of the cultural context from which people derive meaning is an important element of a study. Such cultural context is usually not susceptible to quantification and aggregation and is, therefore, usually ignored in quantitative studies. Yet failure to understand

Figure 4.1: The research stages

Literature review

Input for the interview | **Epistemological assumptions for manufacturing sector**

	Stage	Methodology	Scope	Output
INDUCTIVE	An interview concerning Six Sigma with a medical doctor in two hospitals	Qualitative – Interview	What Health Care organisations are thinking about Six Sigma tools	Key aspects and concepts for grounded theory
	Leading a focus group inside a Health Care public organisation	Qualitative – Focus Group	Better understand the organisation and the way to implement Six Sigma in Health Care	Key aspects and concepts for grounded theory
	Case study	Qualitative – Participant observation	Better understand the organisation and the way to implement Six Sigma in Health Care	Key aspects and concepts for grounded theory
DEDUCTIVE	Definition of the preliminary model	Grounded theory	Collection of the data/information derived from literature review and previous stages. Definition of the preliminary model	Definition of the categories/Preliminary model Finding connections among the categories
DEDUCTIVE	Survey research	Quantitative – Survey as a research method using a questionnaire and Chi-square test	To test and validate the hypotheses through null-hypothesis test	Transformation of the categories into hypotheses Validation of the hypotheses Development of the final model

Development of the Health Care model – Definition of the ten epistemological assumptions for Health Care

Comparison between the two models

	Stage	Methodology	Scope	Output
INDUCTIVE	Review of the first qualitative stage results	Qualitative	To better understand the differences from the manufacturing model and refining the Health Care model	Deeper analysis of the differences found New evidence for future research

cultural context may deprive the researcher of a real understanding of the problem at hand (Kaplan and Maxwell, 1994).

Although most researchers do either quantitative or qualitative research work, some researchers have suggested combining one or more research methods in one study and have called this approach triangulation. Campbell (1974) remarked that all research has a qualitative grounding. There should not be an antithesis between these two methods but rather it should be possible to bring them together to improve any research topic. Several authors have argued about triangulation, for instance Rossman and Wilson (1991) wrote about three particular reasons for using triangulation. The first and most important reason is the possibility of generating new thoughts, analysing paradoxes and unpredicted events. The second is the issue of more details particularly when developing the analysis process. Finally, qualitative and quantitative data should be linked to validate each other. Sieber (1973) suggested that quantitative research can assist in the avoidance of 'elite bias' and correct the 'holistic fallacy'. For example, two medical doctors have been presumed to be Six Sigma experts but they can introduce their personal point of view during the interviews. Building theory directly from the first inductive and qualitative stage could lead to a wrong or distorted model. Validation through a quantitative method introduces a larger consensus on the model. After shaping the model by the means of the quantitative stage, in order to refine the model a further review of the qualitative inquiry results will be done. More details about triangulation can be found for example in Jick (1979), Gable (1994), Kaplan and Duchon (1988), Firestone (1987), Mingers (2001) and Vidgen and Barnes (2006).

4.3.2 The use of a case study

Inside qualitative inquiries and research design, the case study represents one of the most used methods especially in the management sector. In point of fact, some researchers (Stake, 1995) argue that a case study is an object of analysis more than a method. Other authors point out that it is a typical qualitative method of inquiry used as an exploration of a 'bounded system' (Merriam, 1988). According to Creswell (1998), time and place are the boundaries of the case study and the researcher is supposed to use multiple sources of information.

When using a case study a researcher first has to take into serious account if the case can be single or multiple, multi-sited or within-site, focused on a case or on an issue (Yin, 1984). According to Dogan and Pelassy (1990), the use of case studies cannot generate theories in a definitive way. Case studies must be linked to a hypothesis that can then be followed by a deductive path. The use of case studies in this research is justified by the facts that:

- It is possible to obtain outcomes that can be compared with other similar case studies. As a matter of fact, in the following chapter it will be demonstrated how the outcomes of an interview with a doctor of an Italian hospital were compared with the outcomes of two case studies.
- Case studies typically lead to the use of different methods to collect data such as interviews, database, questionnaires and observations. Data can be both qualitative and quantitative, even though only qualitative evidence is analysed in the first inductive stage.

To support the decision to use case studies, a literature review (summarised in the next subsubsections) was performed to show their use and the strong and weak points of this choice.

4.3.2.1 Strong points of the case study method

Many papers discuss the possibility of using case studies to generate theories and hypotheses inside a specific field. Among the first interesting examples are Gragg (1940) and Glaser and Strass (1967). Gragg argued that case knowledge is central to human learning. Glaser and Strass introduced an effective comparative method to develop grounded theories, and they discussed the importance of reality in the possibility to develop accepted and verifiable theories. Some researchers therefore point out how case studies are particularly close to typical real situations and enable collection of the 'soft' sides of human behaviour. Other researchers state that, probably, no predictive theory exists in social studies or management. Social studies and management have never led to the generation of context-independent theories and can therefore only take context-dependent knowledge into account. Campbell (1979) is one of the researchers who support these statements. A quotation from his 1979 (p. 126) book can surely better explain his position:

> *After all, man is, in his ordinary way, a very competent knower, and qualitative common-sense knowing is not replaced by quantitative knowing. This is not to say that such common sense naturalistic observation is objective, dependable, or unbiased. But it is all that we have. It is the only route to knowledge...fallible and biased thought it be.*

Yin (1984) defines case study research as an empirical inquiry that investigates a contemporary phenomenon within its real-life context. Thus case study research becomes particularly important when the boundaries between phenomenon and context are not clearly evident and multiple sources of evidence are used.

As shown in the previous chapter, it is not clear what kind of Six Sigma model could be applied in the European Public Health Care sector and what the differences from the manufacturing sector are. The phenomenon within the Health Care context is not clearly evident when Six Sigma is managed. To find well-founded hypotheses for the Health Care sector it is necessary for the research to collect information using case studies. The information collected is to be compared with the literature review conclusions of the third chapter.

4.3.2.2 Weak points of the case study method

This first part of the research is underpinned by the case study method: collecting information by interviews, a focus group and observations. In the Health Care sector the choice of case studies is limited to the few hospitals that have managed Six Sigma.

The case study presents some weak spots that could affect the research and in this section they are discussed. Campbell (1979), who is one of the strongest supporters of the method, summarises some oversimplifications about the use of such a research method:

- Practical, context-dependent knowledge is not as valuable as general, context-independent knowledge. In order to discuss this first point, it is important to understand that the nature of the research, Six Sigma in Health Care, does not permit today a general knowledge approach.
- It is quite difficult to generalise on the basis of individual cases. This could be a weak spot of the research. Indeed, after shaping some hypotheses these will be tested in the second part of the research using quantitative inquiry.
- It is often difficult to sum and develop theories on the basis of case studies. The case studies are utilised for generating hypotheses and that is suitable in the first stage of a research (Flyvbjerg, 2006).

4.4 Collecting data and information for the case study

As explained above, in order to collect data and information inside the two case studies (two Italian hospitals), the qualitative methods used have been:

- interview;
- focus group;
- observation.

Two medical doctors have been interviewed. The doctors work as quality managers inside the two Italian hospitals. Other data/information have been collected by means of a focus group inside the Pharmacy department of an Italian hospital (Chiarini, 2008). This particular department was chosen because in 2007–2008 a team launched a Six Sigma project concerning cancer drugs. In addition, a team not mentionable for privacy reasons was involved in a short focus group that lasted about one hour. The six participants were not as specialised as the interviewed doctors. Finally, an observation was carried out inside two Italian hospitals based on the implementation of Lean Six Sigma projects.

4.4.1 The first source of data/information: the interview

Two semi-structured interviews have been held. An interviewer's guide was developed before interviewing the medical doctors (see Chapter 5) with some open questions that explored the specific areas of interest (Ethnographic interviewing). According to Holstein and Gubrium (1997) an ethnographic interview includes both 'grand tour' and 'mini-tour' questions:

- 'grand tour' gets an overview;
- 'mini tour' gets details.

During the interview an attempt was made to avoid 'leading questions' and to not try to force the interviewee to accept the positions of the researcher. Indeed the researcher's expertise in Six Sigma was very much in the background. Questioning, therefore, involves in situ analysis: moving backwards, forwards and infilling for depth and detail. The questions used in the 'draft memoire' were all substantially of the open type because closed type questions would not have allowed the interviewee to analyse and discuss unknown aspects. According to Hammersley and Atkinson (1995):

> *A question which sharply defines a particular area for discussion is far more likely to result in omission of some vital data which you, the interviewer, have not even thought of.*

4.4.2 Collecting data: why use a focus group?

To generate hypotheses, it is also important to understand the culture and the organisation of European Public Health Care as well as Six Sigma implementation. The culture and organisation can influence the responses of the interviewees therefore the interview responses were validated through a focus group. For example, the two doctors considered the involvement of union members as absolutely unimportant for the Six Sigma projects. Thus, this was one of the claims better investigated through a focus group. The Ethnography approach was conducted using a questionnaire inside the focus group that comprised members of a Six Sigma team. The facilitator of the group was the researcher. Ethnography is a possible approach to discover systems of meaning, cultures and the results can be reported in the form of a story (Ridley-Duff, 2006), or something else more suitable for the research (for example a description of the organisation processes, shared values, mission and vision, formal and informal objectives, organisation chart etc.). Some researchers (Douglas, 1976), however, have noted that if the researcher participates in the research team then his or her reactions could become part of the data used to develop theory. Weick (1995) argued about the dangers of emotion in research.

The questionnaire used in the focus group was not filled out by the participants but was, rather, a guideline for the researcher. The aims of the focus group are:

- to understand the focus group's culture;
- to gather information about organisational climate, roles, skills, responsibilities and other important aspects.

In particular this latter item does not come out of an interview clearly.

4.4.3 The observation inside two Italian public hospitals

Further data and information has been gathered in the inductive–qualitative stage of the research using two Italian public hospitals as case studies. The first hospital has been conducting a complete and articulated Lean Six Sigma project along with important English consultants. The second one has launched a Six Sigma project inside the Pharmacy Department only. The researcher has gathered data and information as a neutral observer.

The primary scope of observation is to observe participants in as natural a setting as possible (Pearsall, 1965). Observation has been carried out within a group of doctors and paramedics.

The Health Care sector, in particular European Public Health Care, clearly shows a different way of managing matters such as problem solving, authority and skills. The observation has been led in an ethnographic way and direct experience has been chosen (O'Reilly, 2005) within a team in which the group of participants were observed first and then the findings of the observation were discussed with them. The ethnographer has to introduce himself or herself in an unfamiliar territory (Denzin, 1997).

By conducting observation, the researcher learns about what is going on at the same time as he or she is building strong and informative relationships with the group. Observation relies heavily on the researcher's subjective understanding of research situations and because of this the researcher must be aware that it requires a careful balance. The researcher led the observation being both a participant and an observer. Indeed the researcher acted as a consultant giving details about how to manage the projects. The researcher did not interfere with the team dynamics. A mistake that the researcher tried to avoid was to take notes as the dominant part of participant observation and this was mainly due to the researcher also acting as observer-researcher and consultant at the same time. In order to reduce the influence of the researcher, the researcher and the team set precise rules from the beginning, such as:

- The researcher-consultant can only train team members about new tools derived from the DMAIC pattern.
- The results to achieve, timeframe, and tools inside the DMAIC pattern are only chosen by the team leader and senior managers.
- Team members and team leaders cannot be appointed by the researcher.
- Organisational rules and relationships with the senior managers can only be decided and managed by the team leader.
- Team members can suggest to each other every kind of solution for the project. Suggestions can only be discussed with the researcher in a purely technical way.
- Any conflict or organisational problem that arises during the project cannot be managed by the researcher-consultant.

These rules have been fundamental for reducing the influence of the researcher. Indeed, according to Silverman (2004) if the researcher suggests opinions, information or data to the team, this could introduce bias in the outcome of the research.

However, even though the above rules have been set, probably the researcher has influenced the results of the observation in some ways. In particular, the researcher, acting as a trainer as well, might has suggested specific tools and solutions during the training, influencing the team.

The people who are being researched are the experts on their own lives, experiences and situations and the researcher is learning from them (Silverman, 2004). In particular the researcher is:

- participating in and observing what is happening and what is being said and done;
- building a research relationship with people;
- part of the situation that he or she is observing;
- having some impact upon what is happening.

The researcher has to accept that he or she is a part of the research situation and will have to reflect upon and consider his or her role in events. The researcher writes about all of this in field notes. The difference between a observer and a normal participant (in this case a medic or paramedic) is simply analysis and awareness:

- A normal participant will take a lot for granted: this is just how things are done and this latter is obvious.
- Observers try not to take anything for granted. They need to keep the attitude of someone entering a new and strange situation, someone who is trying to understand how things work. Nothing is obvious or let by chance.

The ultimate objective of the ethnographic part of the research is to participate in and observe social situations to the extent that in time a researcher will learn how that situation works and how people understand what is going on. The researcher will be able to understand cultures, social situations, practices and relationships from the points of view of the people he or she is researching, yet at the same time be able to maintain enough objectivity to record the details of any situation and use them to help the initiative develop. The researcher will also learn about himself or herself and learn to challenge his or her own assumptions. The aims of this observation inside the two hospitals are:

- To analyse in detail what kind of tools are better inside the DMAIC pattern.
- To collect important information about how to lead a Six Sigma project in the Italian Public Health Care sector and compare it with Lean Thinking and TQM.
- To gather information about the differences between applications in the manufacturing sector and in the Health Care sector.

In particular, the last item does not clearly come out of an interview or a focus group.

4.5 Grounded theory as a framework for analysis

The first part of the research is inductive and qualitative methods have been used for data gathering and analysis. The results of the interviews, the focus group, the observation and the literature review as well, are collected together to reach some hypotheses. Therefore all is data and the development of the preliminary model follows a process similar to the goals of grounded theory (Glaser and Strauss, 1967). Under a grounded theory approach, theoretical sampling cannot be derived from a precise initial design. At the start of the research it was not known what would allow pattern detection and saturation. In grounded theory, sampling is organised by conceptual emergence and bounded by theoretical saturation, not by a precise design. As Glaser and Strauss (1967, p. 45) explain:

> *Theoretical Sampling is the process of data collection for generating theory whereby the analyst jointly collects, codes, and analyses his data and decides what data to collect next and where to find them, in order to develop his theory as it emerges.*

This process of data collection is controlled by the emerging theory, whether substantive or formal.

This research uses several sources to collect data and in the end to generate hypotheses that are conceptualised and linked through the help of grounded theory.

In grounded theory the literature review is usually conducted after the emergence of substantive theory is carried out. Some authors (Eisenhardt, 1989; Urquhart, 2001) have underlined that it is during this process, and not before, that data from the literature contributes to the research. The approach of reading the literature first with the objective of identifying gaps and relevant theories is opposite to the role that the literature has in grounded theory. According to Glaser (1998, p. 67):

> *...grounded theory's very strong dicta are a) do not do a literature review in the substantive area and related areas where the research is done, and b) when the grounded theory is nearly completed during sorting and writing up, then the literature search in the substantive area can be accomplished and woven into the theory as more data for constant comparison.*

The results from the literature review of the third chapter have been used both for the first inductive stage and for the grounded theory approach. In particular, during this latter stage, the Health Care literature review results have been utilised for the emerging theory (literature as data).

Some authors classify grounded theory as an inductive method (Glaser and Strauss, 1967; Glaser, 1978; Martin and Turner, 1986; Strauss and Corbin, 1990) even though according to Glaser (1998) the notion of induction versus deduction is often a simplification of the complex reasoning pattern present in grounded theory. Grounded theory is both inductive and deductive and leads to theory generation (Eisenhardt and Graebner, 2007) through a first coding and hypotheses-forming stage (inductive part) and a second theoretical sampling stage. This inductive–deductive loop is similar to the previous loop discussed in Section 4.2. In any case grounded theory is not a descriptive method but it helps concepts and hypotheses to emerge (Gloser and Halton, 2004).

According to Glaser and Strauss (1967), a concept is a general element that includes the categories that are conceptual elements standing by themselves, and properties of categories that are conceptual aspects of categories. According to Strauss and Corbin (1990) it is important to use coding to shape the concepts. In grounded theory there are three basic types of coding: 'open', 'axial' and 'selective'. For the purpose of this research, open coding and selective coding have been mostly used to handle the data collected through the qualitative methods.

Open coding is the initial level of abstraction. Information and data taken from interviews, the focus group and other memoires are accurately analysed and conceptualised (Charmaz, 2006). To begin with the most important findings are coded and classified and this produces analytic categories. Everything is coded, including field notes, in order to better conceptualise. Each finding is labelled and the researcher has to find appropriate categories. The categories are then developed and properties and dimensions are found (Trauth, 2001).

In the axial coding stage, data and information are analysed after making connections between categories. In particular, it is important within the categories to identify circumstances and conditions that originate the category, the context into which the category is embedded, interaction and action strategies.

Selective coding is done with the purpose of finding the core category. According to Pandit (1996), the core is the central category around which the final analysis will be based. A story line needs to prioritise one category over all others and these latter are related to the core. Grounded theory is used in this research to analyse linkages among hypotheses that will then be validated through quantitative methods.

4.6 Grounded theory and quantitative methods

Although grounded theory is more associated with qualitative methods (Charmaz, 2003) the researcher can use quantitative methods as well. As noted by some authors (May, 1996; Wilson and Hutchinson, 1996) grounded theory is losing its identity and sometimes its results are obvious and not so verifiable. To be surer about the consistency and the possibility of generalisation of this research result, a quantitative method such as null hypothesis has been, in an original way, used to revise and definitely validate the hypotheses and their connections. Corbin and Strauss (1990, p. 9) wrote:

> *A key feature of grounded theory is not that hypotheses remain unverified, but that hypotheses (whether involving qualitative or quantitative data) are constantly revised during the research until they hold true for all the evidence concerning the phenomena under study…*

This way of using grounded theory, constantly revising data and information gathered from the qualitative stage, represents the specific approach of this thesis to it. An approach closer to a deductive prospective than an inductive one.

Lösch (2006) wrote about how to combine quantitative methods and grounded theory. In Lösch's paper cross-tabulation analysis, analysis of means and other quantitative methods were applied to find out the relationships between buyers and suppliers through a particular electronic system. The conclusions of the paper could be applied to all managerial subjects including Six Sigma.

4.7 Strong and weakness points of the methodology

According to figure 4.1 the research path is based, in the first inductive/qualitative stage, on interviews concerning Six Sigma with two doctors in two different hospitals, a focus group and a case study carried out inside one of the two public hospitals. Therefore the scope of the fieldwork in the qualitative inquiry is not as wide as the survey used in the following quantitative stage. Indeed just a small sample of two hospitals have been investigated, on the contrary more than 500 people have answered to the questionnaire. In fact the large quantity of information and data gathered through the interviews, the focus group and the observation will be analysed just to issue concepts and theoretical categories. Qualitative methods can be used when understanding the cultural context from which people derive meaning is an important element of a study (Rossman and Wilson, 1991). Such cultural context is, usually, ignored in quantitative studies. According to Flyvbejerg (2006), a small sample can be utilised for generating new ideas and consequently hypotheses and that is particularly suitable in the first stage of a triangulation research. In any case the quantitative stage will strengthen the hypotheses derived from the few case studies. Indeed by the means of a chi-square test the hypotheses will be tested and finally validated.

4.8 Conclusions and next steps

The chapter has shown the methodologies used to carry out the research. The results of the literature review bring some clues on what to investigate by the means of the interviews and then by other qualitative tools. In this way the first inductive stage of the research will generate concepts starting from the results of the literature review of the previous chapter. Inductive reasoning has been criticised mainly because, according to Popper (1959), results can be contradicted just by one different experiment. The case study, focus group and observation approaches have been criticised because they try to generate theory through a few cases.

It is fundamental, in any case, to investigate the organisation and culture of the European Public Health Care sector. Qualitative methods can be used when understanding the cultural context from which people derive meaning is an important element of a study. Such cultural context is, usually, ignored in quantitative studies. The results of the literature review show for instance that it is fundamental to investigate:

- the culture and climate organisation of the Health Care sector compared with the manufacturing sector;
- the kind of tools used in the Six Sigma projects;
- aspects such as politics and economic influence.

The first item is tied with observation inside a group dedicated to Six Sigma inside an Italian hospital. The information and data gathered through an interview, a focus group and observation will be analysed to issue concepts and theoretical categories. This analysis is carried out through grounded theory with the aim of discovering links among the categories.
To overcome criticism about qualitative methods and grounded theory, the categories will be transformed into hypotheses and tested in the sixth chapter. This is the part of the research that carries on through deductive–quantitative reasoning. The final model will be compared with the manufacturing one also using the ten epistemological assumptions determined in Chapter 3. The next chapter will show how data/information is collected and analysed by using qualitative methods to generate the grounded theory categories and their links.

Chapter 5 – Data gathering and process analysis using grounded theory

5.1 Introduction

In the third chapter a review of the current Six Sigma literature has shown that a complete and specific European Public Health Care model is missing. In addition, the literature has not yet deeply investigated the real specificity of European Public Health Care. Furthermore, in order to better compare the manufacturing and the Health Care models, ten epistemological assumptions for the manufacturing sector have been defined. These assumptions are the way of implementing Six Sigma in the manufacturing sector and in the end they will be compared with parallel epistemological assumptions for European Public Health Care.

The conclusions of the literature review bring important clues that become inputs for the qualitative inquiry and for the grounded theory approach. Firstly, it is certain that Six Sigma in Health Care needs new tools from other management systems such as Lean Thinking and TQM. Indeed some authors, in particular George (2002), have coined the term 'Lean Six sigma' for this encounter. As explained in the third chapter, Lean Six Sigma is mainly made of new tools from Lean Thinking that are lent to the DMAIC pattern. Thus it becomes important to look into Lean Thinking and not only with the purpose of understanding what kind of tools and in what circumstances they can be used. Secondly, according to some authors (Piper, 2004; Volland, 2005), it is important to investigate the strategic goals that can be achieved by using Six Sigma in the European Health Care sector. In the classic manufacturing model, the principle of saving leads every Six Sigma project; the savings must be higher than the project costs. However, in European Public Health Care it seems that for particular projects savings become less of a priority than, for example, patient satisfaction. Therefore it is also necessary to investigate what the factors are that can affect these decisions.

Last but not least, the skills and the 'climate' within the Six Sigma teams and their organisations could differ from manufacturing ones. In other words, skills, roles, responsibilities and conflicts inside the team and the management, have to be investigated.

These are issues derived from the literature review and they are surely not enough to explain all the differences from the manufacturing sector and to shape a new model. As explained in the fourth chapter, the outcomes of the literature review have been used both as input for qualitative inquiry and data for grounded theory. This latter is just used as a tool in order to rationalise all the data and information gathered from the inductive – qualitative stage.

The data gathering for the grounded theory has been carried out through two interviews, a focus group and participant observation. The process concerning data gathering is described in this chapter.

5.2 The interview

According to Flyvbejerg (2006), a small sample can be utilised for generating new ideas and consequently hypotheses and that is particularly suitable in the first stage of the research. In order to generate such ideas, at this stage the most important thing was to interview Health Care professionals very into Six Sigma. In this way two Italian doctors that carried out Six Sigma projects were chosen.

Before interviewing two medical doctors an interviewer guide was developed. A semi-structured interview has been used. The interviewer guide contains some open questions that brought into exploration specific areas of interest (ethnographic interviewing). The interviewer guide 'memoire aid' of the interviews can be found in Appendix A.

Table 5.1 shows the areas of interest that were developed in the interviewer guide. The areas were derived from the literature review and have been utilised for the focus group as well.

5.2.1 The process of interviewing

The interviews lasted about three hours each and they were conducted in the office of both the medical doctors. The use of digital recording was set aside because it could have made the interview very formal and the interviewees might have found it disturbing. During the interviews 'leading questions' were avoided.

Table 5.1: Main areas of interest for the interview and focus group

Area	What to investigate
Specific tools for Health Care	What kind of tools and in what circumstances they are applied
Objectives connected to Six Sigma improvement projects	What kind of objectives the team should achieve and what the reasons and the influences are
Organisational climate	'Climate', skills, training, management, rules and so on for Six Sigma implementation

5.2.2 The purpose of the interview

The tendency of interviewees is often to waste time with extraneous matters or, even worse, to drive the interview towards questions that do not have anything to do with the subject. The purpose of the interviews has been entirely respected; in no way were extraneous matters taken into account and the medical doctors were brought more times on the principal run. As an instance, to the question regarding the use of statistical advanced tools within the precise project, a fundamental question to validate some of the hypotheses, one of the interviewees avoided the possibility to use them in every case. However, this is a typical extraneous answer because the interest is just to know if they had been used or not in the Six Sigma projects.

Impression management theory states that any individual or organisation must establish and maintain impressions that are congruent with the perceptions they want to convey to their public (Goffman, 1959). One of the most important aspects to such a purpose is to make sure that the interviewer is perceived as an expert of equal or superior level. In cases in which the interviewee perceived a certain weakness from the interviewer there would be the opportunity for the interviewee to waste time in the introduction of the matter or, even worse, to lose trust in the abilities of the interviewer. This last situation would practically have brought the interview to a complete failure.

5.2.3 Mechanics of the interview

The first questions of the aide memoire have been useful to evaluate both the knowledge of the interviewees concerning Six Sigma and the relationship with the topic. As expected, the interviewees were particularly experienced in Lean Thinking and TQM but less so in Six Sigma, however, they were very stimulated by the matter because they are experts in the subject.

The answers were annotated in a notebook underlining the key concepts for a following grounded theory analysis. The written concepts were linked by a question mark ('?') when they needed closer examination and underlined when they were directly connected to the possibility of being coded.

The questions of the draft-memoire are all substantially of the open type. This is because questions of the closed type would not have allowed the interviewee to analyse and discuss unknown aspects. According to Hammersley and Atkinson (1995):

> *A question which sharply defines a particular area for discussion is far more likely to result in omission of some vital data which you, the interviewer, have not even thought of.*

The answers and the following grounded theory analysis have produced new elements of theory for the thesis. Geertz (1973) used the term 'thick description' to refer to ethnographic fieldwork in which the descriptions made by the anthropologist are not only detailed and 'factual' (although they start from what is observed and experienced) but are beginning to be theorised, as events and interactions are described within contexts.

In addition, the open questions facilitate the discussion with the interviewee and bring the so-called reflective confrontational interviewing. The interviewer and the interviewee discussed every answer with the purpose to individualise additional elements or to modify some aspects in semiotic elements.

Because the research next stage is strictly deductive, with hypotheses to be tested, the interviews brought an inductive way of generating some new theoretical elements.

5.2.4 Outcomes of the interviews at a first glance

The two interviews led firstly to the conclusion that a Six Sigma model dedicated to Health Care necessarily has to be different from the classic manufacturing model. The potential key aspects stated by the two doctors are:

- There is a great influence from local politicians inside the Regional Health Care Department. The patient is first of all a citizen who votes for the local politicians.
- The patient wants the best cures at the lowest price; in any case good quality of services is expected.
- The General Manager is appointed by local politicians and often is not a medical doctor.
- Process time is something very fundamental to Health Care; it increases patient satisfaction and consequently it is important for the Regional Health Care Department.
- Six Sigma teams rarely use advanced statistical tools for the attainment of their projects.
- Nevertheless, advanced statistical tools (DOE, ANOVA, Multiple Regression, RSM, etc.) can be used in the case of projects where it may be necessary to investigate the factors that affect an output. For example, such projects can concern the factors that affect infections, the quality of drugs and so on.

- Staff members nearly never have a basic engineering education and some know nothing at all about statistics.
- Nevertheless, a staff member owning a Black or Green Belt certification has always been present within the project team.
- However, such a staff member was trained according to a training course that was more suitable for the manufacturing field. Apparently, there are no specific training courses for Black and Green Belts in the field of Health Care.
- The greatest emphasis was put on managerial and/or problem-solving tools such as Pareto Analysis, Cause-Effect Diagram and 8D problem solving.
- The tools used during the DMAIC pattern need to be enriched. In particular, it is better to use VSM, Makigami and other tools 'borrowed' from Lean Thinking such as 5S, TPM, Heijunka and Poka-Yoke in Health Care processes.
- The targets to achieve are not always linked to economic or financial savings. The customer's satisfaction represents the major target due to ethical reasons that can lead to neglect of merely economic factors.
- The targets pursued by Six Sigma projects can also derive from national or local laws regardless of the strategies of the organisation.

Summarising the outcomes of the interviews it is possible to state that a hypothetical Six Sigma model for the field of Health Care implies the achievement of different targets (managerial, political and legal), the use of teams with a less statistical and engineering specialization, and the achievement of targets often linked to the customer's satisfaction. Particularly interesting is the fact that, according to the two managers, advanced statistical tools are rarely used but are not to be excluded 'a priori'. Their use depends on the type of project. Among the outcomes of the interviews, the results on the use of tools 'borrowed' from Lean Thinking are of capital importance.

5.2.4.1 Grounded theory open coding for the interviews

Grounded theory open coding is the first step of grounded theory. The answers to the interviews are deeply analysed word by word and the phenomena should be labelled and the words and phrases are highlighted and stated in a short phrase. This short descriptor is a code and Glaser and Strauss (1967) pointed out that coding is a process that has to be carried out without preconceived ideas. Naturally after reading the interview answers several codes emerge from the analysis and the researcher is supposed to code and re-code several times. Table 5.2 shows the first open coding of the interviewees answers.

Table 5.2: Labelling the key aspects of the interviews

Label	**Key aspect from the interviews**	**Code**
I_1	Senior managers sometimes follow political will because local politicians decide their careers	Senior managers follow political will
I_2	Funds for the hospitals come from their local authority and this latter have to fulfil voters' needs	Funds received from local authority
I_3	Citizens want the local authority's funds to be spent on the best health care. A relevant part of their taxes is for the health care system	Funds from citizens' taxes
I_4	Public hospitals have a business plan where strategic objectives are agreed with the local authority	Strategic objectives are agreed with the local authority
I_5	The general manager is not a medical doctor and the length of her/his appointment is controlled by local politicians	Local politicians appoint general manager
I_6	Senior managers are directly involved in politics and they sometimes belong to a political party	Senior managers are involved in politics
I_7	Citizens vote for political parties and their political representatives inside the local authority. Citizens also vote on the basis of the health care strategic programme	Strategic programmes are voted by citizens
I_8	Economic goals are important but are not	Balancing economic and

	fundamental to fulfil patient satisfaction	patient satisfaction goals
I_9	Patient satisfaction is a right because citizens pay taxes and this is for them enough to claim good health care. Citizens reckon that their taxes are enough for receiving good health care	Good health care is a right
I_{10}	Results of Six Sigma projects must be aligned with political objectives	Six Sigma results aligned with political objectives
I_{11}	At the end of a Six Sigma project economic results are important but they are not ever measured in an accurate way	Economic results measured in an imprecise way
I_{12}	Doctors and nurses do not usually have a mathematical background and they are not used to statistical tools	Absence of mathematical background
I_{13}	Statistics and maths are difficult to understand and use, therefore it is not so simple to certify Black and Green Belts, particularly using advanced statistics	Statistics and maths are difficult to understand
I_{14}	Several Six Sigma classic tools, including advanced statistical tools, are strictly oriented to problem solving and not to the flow	Statistical tools for problem solving and not for the flow
I_{15}	Data are different from manufacturing. Several times we are talking about time and quantitative attributes instead of variable measures within the flow	Time and quantitative attributes instead of variable measures
I_{16}	We do not use physical instruments such as gauges. Consequently some statistical tools such as Gage R&R and ANOVA are less important	Less or poor use of statistical tools for physical instruments
I_{17}	Process time is fundamental for health care. Everyone asks for time reduction: patients, local politicians, senior managers, doctors and nurses. Time is	Time and the flow as a whole are the most important factors

	the most important measure. So it is better to understand how to analyse the entire flow instead of the single process. In this case Lean Thinking tools are welcome	

The next stage is the analysis of the codes and grouping together in a common driver. This higher common driver is called a 'concept'. Table 5.3 summarises the process that has led to the grouping of the key aspects given in Table 5.2.

Table 5.3: Grouping the key aspects of the interviews into concepts

Block of properties and dimensions	Concept	Group
1	Senior managers are related to local politicians	I_1, I_5, I_6
	Strategic objectives derived from local authority	I_4, I_7
	Funds from local authority	I_2, I_3
2	Economic results measured in an imprecise way	I_{11}
	Economic results balanced with good quality	I_8, I_9, I_{10}
3	Less statistical background	I_{12}, I_{13}
	Statistical tools for 'limited' aspects not for the flow	I_{14}, I_{16}
	Process time first of all	I_{15}, I_{17}

5.2.4.2 Emerging categories from the interviews

At this stage, concepts are compared with each other and properties and dimensions of the concepts are discovered. Table 5.3 presents the grouping of concepts using similar properties and dimensions; this is the axial coding process. The first concept block has, for instance, a strategic dimension and a social–political property. Thus, matching the first three concepts, a category can emerge: 'Strategic objectives linked to local authority'. Proceeding with such reasoning, two other categories emerge from the second and third block as shown in Figure 5.1:

- Economic results balanced with other factors.
- Statistical tools in general less suitable for Health Care.

Figure 5.1: Categories derived from the interviews

Category	**Concept**
Strategic objectives linked to local authority	Senior managers are related to local politicians
	Strategic objectives derived from local authority
	Funds from local authority
Economic results balanced with other factors	Economic results measured in an imprecise way
	Economic results balanced with good quality
Statistical tools in general are less suitable for the Health Care flow	Less statistical background
	Statistical tools for 'limited' aspects not for the flow
	Process time first of all

5.3 Focus group

The focus group has been used in order to provide clarification and expansion of the data gathered during interviews. Although group interviews are often used simply as a quick and convenient way to collect data from several people simultaneously, focus groups explicitly use group interaction as part of the method (Kitzinger, 1995).

After conducting the interviews, leading a focus group has helped the researcher to widen some phenomena and be able to define patterns of behaviour across the wider audience. The focus group was carried out inside an Italian public hospital and this latter and the names of the participants cannot be disclosed according to Italian privacy law. It was based on a debate with a 6-member team on the way to manage a Six Sigma project in the field of Health Care. The researcher used the questionnaire shown in Appendix B as a guideline. The first part of the questionnaire helps the researcher to understand the knowledge level of the participants. The second part is the most important one in which the team debate on aspects such as rules, roles, organisational climate and conflicts within the team.

5.3.1 Comparison with the outcomes of the interviews

The questionnaire initially permits focus on some particular aspects, such as the knowledge of the members of the focus group on the general concepts of Six Sigma and job descriptions and rules inside the teams. It was useful to understand if the interlocutors mastered such knowledge or not. Less specialised topics were discussed during the following debate with the team members with a lower level of knowledge of Six Sigma.

The first important entry that emerged from the focus group was that formality and compliance with rules tend to transform the perception of hierarchy. In a manufacturing company sometimes it may not be so easy to distinguish managers from the other staff members in a team. In Italian Public Health Care it is much easier to distinguish the Head in charge from medical doctors and nurses. In the field of Public Health Care, team members show respect towards the senior management who therefore can sometimes acquire a natural appointment as team leader. Even if nurses have respect towards Head of Departments they sometimes claim a better managerial role inside the teams. A Head of Department can directly carry out a project even with no formal approval from the General Manager. Thus the power of such a manager in Italian Health Care is large. The manager can also establish the duties of all remaining participants. Nevertheless, participants were not satisfied with their roles inside the Six Sigma project because these kinds of responsibilities are not well established in a contract. This is a heritage of the typical medical education for both doctors and nurses.

Participants in the focus group also discussed that the objectives for the projects are usually related to the hospital's strategies; the patient is the main focus and the objectives are not only those of the Department. This can happen whether Six Sigma is not a project of the entire hospital. The Head of the Department is involved in the budgeting stage, in order to decide the total amount of the costs and the objectives with the General Manager. But he or she can autonomously decide the kind of improvement projects and the tools alongside his or her staff. Therefore many notes led towards the direction of a strong commitment of the Head in charge. For example, a participant claimed several times during the focus group: '*this is the project of our Head of Department*'; the Head of Department himself said '*this is a project of mine, even though I made the decision with my staff*'.

The focus group can also rely on some important notes concerning the skills and qualifications of the participants. This is another case in which respect for the privacy law is important. The observer has to require a formal consent or previously ask for it. The notes written down have definitely shown that:

- None of the participants has got a technical degree (e.g. engineering). This is expected in a typical Health Care sector.
- The knowledge on advanced statistical tools is poor.
- The knowledge on other tools less related to statistics such as FMEA, Pareto, Cause and Effect diagram and 5 WHYs is deeper than the knowledge on advanced ones. These tools have been used in other projects especially concerning Risk Analysis.
- In any case there is a consensus about the possibility to use advanced statistical tools inside particular projects in which many factors could affect the response (e.g. reducing the infections post-hospital).

In addition, some participants discussed the typical manufacturing path to achieve the Black Belt certification. Concerning this latter subject, the participants claim that the path does not fit the field of Health Care; it is intricate, full of tools for technicians and engineers. Six Sigma in the Health Care sector needs less statistics and more managerial tools.

The outcomes of the debate inside the focus group led to the confirmation of part of the points that emerged during the interviews, in particular:

- The use of advanced statistical tools only in the case of particular projects.
- The use of tools taken from Lean Thinking for the entire flow.
- The centrality of customers, often to the detriment of economic–financial outcomes.

It is interesting to note how, according to most participants, the team actually has to use tools suited to the kind of problem that has to be solved (Chiarini, 2009). It is therefore necessary to override the process forcibly introduced by the classic manufacturing model, according to which most tools are to be nearly automatically used.

These findings confirm the results that emerged from the literature review on Six Sigma and from the interviews. It particularly confirms the use of Lean Thinking tools in the DMAIC pattern.

5.3.2 New categories from the focus group

Leading a focus group has brought new important aspects especially concerning organizational climate. Some members of the focus group have reported that inside Six Sigma teams some people have no experience of the role. Six Sigma roles are something new and therefore not yet included in the job descriptions. This can lead to members' demotivation. Linked to this aspect is the professional growth of nurses in the past decades. Nurses have developed professionally and their managerial roles are quite similar to the medical doctors' roles. This can bring about demotivation and conflicts inside the Six Sigma team and consequently the situation can oppose the attainment of the results. The focus group's members assert that is important to issue a precise guideline about how to appoint responsibilities and divide roles within a Six Sigma team.

Department Heads shall issue responsibilities and decide job descriptions. If the Six Sigma project crosses departments, then responsibilities and rules should be agreed with other Heads of Departments or even with the General Manager. Conflicts inside senior management are an obstacle to the success of a cross-department project. Finally, according to the focus group members, the organisational aspects can be summarised as:

- a recognised leadership to senior management;
- a precise appointment of roles inside the team;
- a wider set of job descriptions, especially for nurses;
- a particular attention to conflicts and demotivation within teams.

These aspects are important in the manufacturing sector as well but in European Public Health Care they are emphasised by factors such as employment contracts and conflicts between doctors and nurses.
Last but not least, elements about trade unions have come out during the focus group discussion. It seems that a stronger presence of trade unions inside a public hospital can be related to conflicts between doctors and nurses and can reduce flexibility to perform new roles and responsibilities. One of the points of discussion during the focus group has been: '*being a Six Sigma expert is not my job because I'm not paid to do this*'.
Reviewing and analysing the results of the focus group, a transcript using simply a notebook, the grounded theory approach has pointed out firstly concepts and then categories as shown in Tables 5.4–5.6.

Table 5.4: Labelling the key aspects of the focus group

Label	Key aspect from the focus group	Code
F_1	Conflicts between doctors and nurses can occur within a Six Sigma team. They can negatively affect the results of a Six Sigma project	Conflicts between doctors and nurses
F_2	Heads of Department are recognised as natural leaders. In any case, roles and responsibilities should be clearly defined and negotiated	Clear roles and responsibilities
F_3	Doctors and nurses' contracts do not contain roles and responsibilities concerning Six Sigma or other similar tasks. They are not supposed to perform such jobs	Strict doctor and nurse contract
F_4	During the past years nurses have increased their managerial skills overlapping doctors' responsibilities. This could lead towards conflict and a not so clear situation in term of skills inside a Six sigma team	Nurses' skills overlap with doctors'
F_5	There is no extra remuneration for conducting Six Sigma projects	No extra remuneration for conducting Six Sigma projects
F_6	The trade union is a strong defender of National Health contracts for doctors and nurses. Sometimes it is difficult to work beyond your skills. You can risk conflicts with other employees. Typically you can enlarge and rotate your job only by trade union negotiation	Trade union negotiation for job enlargement and enrichment
F_7	Public Health Care is full of interesting projects such as Six Sigma that last as long as the Head of the department remains in charge	Projects tied to the Head of department and other senior managers

F_8	Public Health Care is full of interesting projects such as Six Sigma that last as long as the General Manager remains in charge	Projects tied to the General Manager
F_9	A Six Sigma project can involve all the hospital only if the General Manager makes a commitment. In any case the General Manager has to involve all the senior management otherwise the project can fail or it can be applied just in some departments	Commitment and involvement of all the Heads
F_{10}	Some Heads of Department have greater power than others. The General Manager is sometimes unable to involve all the senior management and this can limit Six Sigma application	Limits in Six Sigma application due to Heads

The key aspects found and analysed through the focus group were then grouped into concepts as shown in Table 5.5.

Table 5.5: Grouping the key aspects of the focus group into concepts

Block of properties and dimensions	**Concept**	**Group**
1	Doctors and nurses' conflicts	F_1, F_4
	Defining precise roles and responsibilities	F_2, F_3
	Role of the national contract and trade union	F_5, F_6
2	Six Sigma starts and ends with one or few senior managers	F_7, F_8
	Six Sigma not applied in the hospital as a whole	F_9, F_{10}

At the end of the focus group three new categories emerged as shown in Figure 5.2.

Interviews and the focus group are a sort of 'told stories' from other people. An observation inside two Italian hospitals that have applied Lean Six Sigma can surely bring other interesting aspects and phenomena for grounded theory analysis.

Figure 5.2: Categories derived from the focus group

Category	**Concept**
Climate and rules can affect results	Doctors and nurses' conflicts
	Defining precise roles and responsibilities
	Role of the national contract and trade union
Six Sigma should be applied across the whole hospital	Six Sigma starts and ends with one or few senior managers
	Six Sigma not applied in the hospital as a whole

5.4 Observations inside Italian hospitals

As seen in Chapter 4, the observation completes the collection of data and information concerning case studies. The targets of this observation are:

- to collect important information on how to lead an improvement project in the field of Health Care;
- to gather information on the differences between applications in the manufacturing and public sectors;
- to understand their own culture.

The Health Care industry, in particular Italian Health Care, clearly shows a different way of managing matters such as problem solving, authority and skills.

In addition, it has to be taken into serious account that the 'product' is a patient and this can completely change the way to manage processes.

The observation was led in an ethnographic way and directly experienced within Six Sigma and Lean teams. In such a group the participants were first observed and then particular findings of the previous observation were discussed with them. The following subsections show the outcomes and aspects that emerged from the observation.

5.4.1 The first Italian hospital

This first Italian hospital is a so called 'ASL'. ASL is an Italian acronym that in English stands for 'Local Health Care Organisation'. In Italy there are several districts and each ASL provides health care services for one or more districts. The ASL in question was established in 1995 according to an Italian Law that introduced the National Health Care Service. The ASL provides its services to 33 municipalities for 800,000 citizens and it is one of the largest and oldest Italian Public Health Care organisations.

5.4.2 The project inside the hospital

The ASL has been implementing both Lean Thinking and Six Sigma. At the beginning, the organisation launched only Lean Thinking and after one year Six Sigma was launched. The inputs that led the organisation towards an improvement using Lean Six sigma were in brief:

- A formal request from the Health Care local authority. In particular the local government believe that patients/citizens should be satisfied concerning:
    - waiting list times;
    - mistake reduction.

- The necessity of cutting back Health Care costs. This latter issue directly derived from the National Health Care System.

- The appointment in 2007 of a new General Manager who came from a manufacturing company. This senior manager had previously experienced Lean Six Sigma principles.

As mentioned above, the improvement project was initially based only on Lean Thinking and it was named 'OLA' that stands for Lean Organisation for Health Care. For implementing Lean Thinking, the ASL worked with Professor Daniel T. Jones co-author of the famous book *Lean Thinking* and expert on health care process improvement. The ASL has also met with other Public Health Care organisations that have implemented Lean Six Sigma such as Bolton Hospital in the UK. Recently, some hospital's doctors have participated as speakers in several European conferences in order to compare their experience.

5.4.3 The second Hospital and its Pharmacy Department

The second hospital provides its services to 36 municipalities for about 374,000 citizens. The hospital is highly specialised and within its buildings there is also the Medicine Faculty of the University.

The Six Sigma project was launched in 2008 but, in contrast to the other hospital, it was limited to the Pharmacy Department especially the processes about cancer drugs. The Pharmacy Department stores, handles and delivers these drugs to other departments. Despite the project being limited, it received sponsorship from the Hospital General Manager and led to about 1 million euro of savings, increased safety and reduced health risks both for operators and patients (Chiarini, 2009). The team was supposed to solve problems in the delivery of antiblastic drugs that are quite dangerous for the operators that handle them. Discussion about the results of the project can also be found in academic literature (Chiarini, 2012).

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5.5 Results of the observations from the two hospitals

Both the case studies show how 'lead time' is fundamental in the Health Care industry. First, reducing lead time in Public Health Care means that the 'product' (patient) spends less time in the hospital. A long stay, indeed, could affect the possibility to come down with an illness and contract infections. In any case the patient wants a short-lasting flow (stay) and local politicians impose waiting-list time reduction as a strategic objective on General Managers. As in the manufacturing sector, lead time is also linked to saving. Patients 'absorb' several direct and indirect costs during their hospitalisation. Whichever is the Six Sigma or Lean improvement, quality for the caring processes must be without any doubt excellent. Thus, cost and lead time reduction projects cannot affect the quality of the outcome. Zero-defect is an imperative.

But what are the tools for simplifying the flow and reducing lead time? The first hospital teaches that Lean tools are fundamental for this scope and they have been used in many departments with positive results. Both the hospitals, for instance, have analysed patient flow through VSM (see Chapter 3) in the earlier stage of the project. This particular tool borrows from Lean Thinking and enables managers to analyse flows in general in their 'as is' states. Health Care teams, using this tool, can afterwards design a future improved state. 5S for setting in order and cleaning are always used, as well as one-piece flow and SMED (see Chapter 3). Both the hospitals confirm that Six Sigma tools that are based on statistics are preferred for problem solving. Six Sigma advanced statistical tools are fundamental to analysing factors that affect particular responses such as infections, illness and queues. The first hospital for example, wanted to investigate the root causes of complex phenomena, such as variability in staying in hospital; in this case many factors influenced the outcome and the analysis has been performed using advanced statistical tools.

In this manner both the hospitals do not use Six Sigma statistical tools for analysing and speeding up the entire flow. It is thought provoking that the Pharmacy Department has for every Six Sigma project used risk analysis tools such as FMEA and Fault Tree Analysis (FTA). Risk analysis should be a constant of every improvement project in Health Care because the patient is the product and processes must be never failing. Mistake-proof tools are sometimes used for making processes that have zero defects. Finally within the two case studies it can be noted that the DMAIC pattern it is not always strictly followed. DMAIC becomes a precise roadmap when the team has to manage a long and complex project. DMAIC can be deconstructed into its own rules when projects are very short and just based on Lean or a few TQM tools. In this latter case, the projects do not need the skills of Black and Green Belts and the projects can be conducted under a pure Lean or TQM pattern.

5.5.1 Grounded theory open coding for the observations

Reviewing and analysing the results of the two observations, the grounded theory approach has pointed out concepts and then categories as presented in Tables 5.6 and 5.7.

Table 5.6: Labelling the key aspects of the observations

Label	Key aspect from the observation	Code
O_1	It is fundamental to reduce lead times inside the patient flow. This could affect the possibility to come down with some illnesses and contract infections	The shorter the flow, the less infections and illnesses
O_2	Lead times are important for cost reduction. Patients ‘absorb’ several direct and indirect costs during their hospitalisation	The shorter the flow, the less the costs
O_3	Analysing patient flow and reducing lead times affect waiting list time reduction	The shorter the flow, the more patient satisfaction
O_4	Patient always wants a short-lasting whole flow	Patient wants a short-lasting flow
O_5	Tools borrowed from Lean are more specific for simplifying the flow as a whole. They are very fit to analyse the patient flow	Tools from Lean are better for flow as a whole
O_6	In order to analyse patient flow ‘as is’ and design a future improved state just Lean tools such as VSM and other mapping tools (e.g. Makigami) can be used	Tools for mapping are better for analysis and design
O_7	Quality of the caring processes must be excellent. Zero defects is a must	Zero defects on the caring processes is a must
O_8	Each Six Sigma project dedicated to	Risk analysis for caring

	caring processes should be analysed by risk analysis tools such as FMEA and FTA	processes
O_9	Whichever is the Six Sigma project dedicated to caring processes it cannot be affected by 'mistake proofing' tools	Mistake-proofing tools for caring processes
O_{10}	Six Sigma tools that are based on statistics are typically preferred for problem solving	Statistics tools are better for problem solving
O_{11}	Six Sigma tools that are based on advanced statistics are fundamental to analysing factors that affect particular responses such as infections, illnesses and queues	Advanced statistical tools are better for analysing factors in particular situations
O_{12}	Six Sigma statistical tools are not fit for analysing the entire patient flow. They are more used inside a process or activities	Statistical tools are not fit for analysing the entire flow
O_{13}	Whichever are the tools, DMAIC can be used	DMAIC as a framework
O_{14}	If the project is complex, then teams need to have a precise roadmap to follow such as DMAIC	DMAIC fundamental to complex projects
O_{15}	DMAIC path can sometimes be very short (less than one week). In this case DMAIC rules and results are less formalised	The shorter the project, the less formalised DMAIC
O_{16}	DMAIC pattern can sometimes be very short (less than one week). In this case the organisation can use just Lean Thinking tools and Black and Green Belts are not necessary inside the teams	Projects that are very short and based on Lean do not need Black and Green Belts

Notes from the field are less dispersive because a Six Sigma expert has led the observation. It is simpler to move the key concepts from grounded theory to categories because of the researcher's ability to immediately pick up the important information and data and classify the phenomena (see Table 5.7).

5.6 Selective coding for linking the hypotheses – the preliminary model

Selective coding is the process done with the purpose of finding the core category. According to Pandit (1996), the core is the central category around which the final analysis will be based. A story line needs to prioritise one

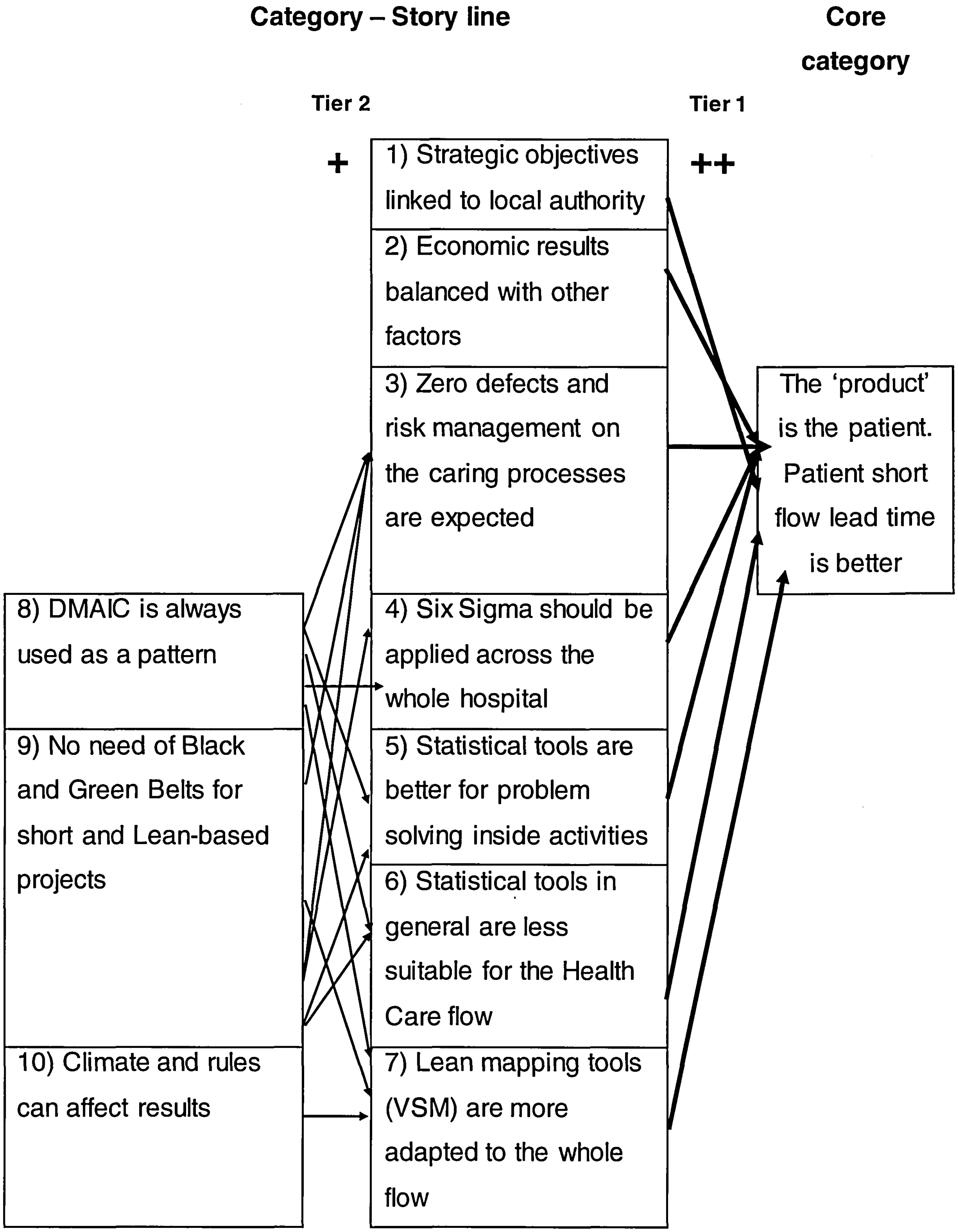
Table 5.7: Categories of the observations

Block of properties and dimensions	**Concept–Category**	**Group**
1	The 'product' is the patient. Patient short flow lead time is better	O_1, O_2, O_3, O_4
2	Lean mapping tools (VSM) are more adapted to the whole flow	O_5, O_6
3	Zero defects and risk management on the caring processes are expected	O_7, O_8, O_9
4	Statistical tools are better for problem solving inside activities	O_{10}, O_{11}, O_{12}
5	DMAIC is always used as a pattern	O_{13}, O_{14}
6	No need of Black and Green Belts for short and Lean-based projects	O_{15}, O_{16}

category over all the others and these latter are related to the core. After coding and assembling data into categories it is difficult to understand what the most important categories are; everything seems fundamental. The researcher must try to prioritise one category over the others. One category must be more central and the others should be related to the core category. The relationships that form the story line are based on context, consequences, results and so on. In this case the story line is based on consequences and the relationships are shown in Figure 5.3. The core category is:

'The product is the patient. Patient short flow lead time is better'.

Figure 5.3: The story line and relationships among the categories or theoretical principles



Consequently the other categories are linked following their relationship degree. In this scope the categories have been divided in two tiers. Tier 1 is formed by categories that have a stronger relationship (identified with ++) with the core. Tier 2 categories have a strong relationship with Tier 1 but less with the core (identified with +). For example, following the scheme from left to right, the category 'DMAIC is always used as a pattern' affects the categories:

- Zero defects and risk management on the caring processes are expected.
- Six Sigma should be applied across the whole hospital.
- Statistical tools are better for problem solving inside activities.
- Statistical tools in general are less suitable for the Health Care flow.
- Lean mapping tools (VSM) are more adapted to the whole flow.

As discussed in the previous chapter, each of the categories can be considered as a hypothesis for the European Public Health Care model, starting from the core category: 'The product is the patient. Patient short flow lead time is better'

Grounded theory has therefore been used in this research to analyse linkages among hypotheses that will now have to be validated through quantitative methods. The researcher is not, indeed, sure that these hypotheses are 'true'. The categories linked together represent the theoretical principles of the preliminary model.

Grounded theory helped theory emerge from data and information from the literature, interview, focus group and case study but, according to the considerations discussed in the fourth chapter, the theory needs to be validated through deductive–quantitative methodologies. These important results can be considered as a preliminary model. It shows that the important difference between manufacturing and the Health Care sector is the kind of product, in other words health care processes are dedicated to a patient. This is a fundamental difference because strategies, flows, improvement projects, expected results, skills, roles and responsibilities should be oriented towards this core focus. In the seventh chapter, after quantitative–deductive validation of the hypotheses, this preliminary model will be compared with the ten epistemological assumptions found for manufacturing.

5.7 Conclusions

In this important chapter, data and information have been gathered through qualitative–inductive inquiries. In particular, an interview, an anonymous focus group and two observations inside public hospitals have been carried out. The interview with Lean Six Sigma expert doctors has been led through a questionnaire based on the results of the literature review. The results of the interviews show general aspects of Six Sigma in European Public Health Care such as political relationship, strategic objectives, senior management involvement and skills inside the teams. The focus group, carried out in a hospital that wants to remain anonymous, suggest important findings about skills, organisational climate, responsibilities and rules inside Six Sigma teams. Finally the observations inside the two hospitals introduce important elements about patient flow, tools borrowed from Lean Thinking and DMAIC pattern. In this way, data and information gathered have been analysed and categorised through grounded theory. Analysis has led to first, a definition of codes; second, a definition of categories and finally to the selective coding process. In this process, theory has emerged in an inductive way and a core category has been established. Strategies, flows, improvement projects, expected results, skills, roles and responsibilities are linked to the core category 'patient'. Figure 5.3 shows links among the categories and has emerged as a preliminary model. According to grounded theory principles (Glaser and Strauss, 1967), research could be terminated because a theory has been already defined. However, in a very original way, in the next chapter the emerged categories will be transformed into hypotheses and tested through a quantitative–deductive methodology. Indeed, the researcher is not sure that these categories are 'true' because they reflect the thought of some doctors and nurses inside Italian hospitals. Quantitative methods can surely generalise and validate the theory.

Chapter 6 – Validation of the hypotheses

6.1 Introduction

In the fifth chapter, through a grounded theory approach, theory about Six Sigma in European Public Health Care has emerged. The inductive analysis using grounded theory was started using the results of qualitative methods: interviews, a focus group and participant observation. Furthermore, the results of the literature review in the third chapter have provided some information used both for interviewing and for grounded theory. The core category found shows how important the patient is and the possibility of reducing his/her flow lead time, or the stay inside the hospital. Linked to the core category the story line in the fifth chapter shows ten particular categories that shape a preliminary model. This model is considered preliminary because the theory or supposed theory derives from the point of view of two interviewed doctors and groups inside two hospitals, and consequently needs generalisation. The emerged theory is the theory of a small group of doctors and nurses inside just two Italian hospitals. Therefore it is important to validate these results transforming each of them into hypotheses. The next sections describe the stages of the survey carried out in order to deeper analyse and validate the hypotheses. The survey is based on a questionnaire given to several academics and practitioners during the past five years. The collected results have been analysed, tested and interpreted by the means of a Chi-Square test. Thus this chapter follows a precise deductive approach using quantitative methods.

As the next section will show, not all the categories of the grounded theory story line have been tested; in fact, two of them have been taken for granted. The categories–hypotheses have been numbered from 1 to 10. Hypotheses number 1 and 2 are taken for granted because they are universally accepted and related to the particularities of the Italian Health Care system. For instance, Hypothesis 1 was related to the influence of the local authority on strategic objectives and this situation is well known and debated in the Italian Public Health Care system.

6.2 The survey design

According to several authors (Babbie, 1990; Black, 1999; Sapsfrod and Jupp, 1999; Bryman, 2001), the survey is a method of gathering information/data from a sample of individuals. The sample is usually just a fraction of the population being studied. The survey method used for this research is a cross-sectional study (Bryman, 2004). Cross-sectional surveys are used to gather information on a population at one point in time (Babbie, 1990). The questionnaire will collect data on what different interviewees think about Six Sigma in European Public Health Care. The cross-sectional survey questionnaire tries to determine the relationship between two factors: Six Sigma application sector and view of interviewees. The body of data collected is then analysed to find a pattern of association. According to Bryman (2001) the steps of the survey to be carried out are as represented in Figure 6.1. The survey steps are discussed in the next subsections. Each subsection deals with one or more steps and shows the results achieved by the research.

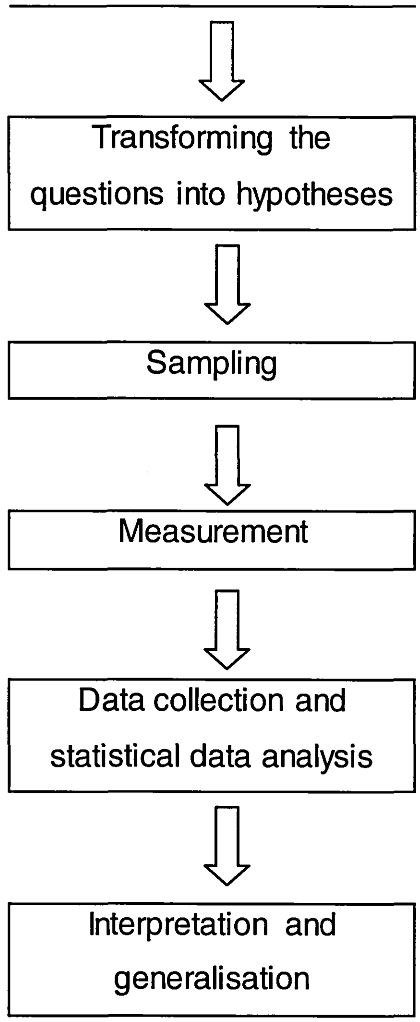
6.2.1 The research questions

The research question is the important statement from which starts the research. The researcher has to have clearly in mind what are the problems and questions to analyse otherwise the research can head towards wrong directions. According to Bryman (2001, p. 33), in order to exactly define what the questions are the researcher should follow the suggestions below:

- *be clear;*
- *be concise;*
- *be researchable;*
- *connect with established theory and prior research;*
- *link research questions;*
- *make a contribution to knowledge;*
- *do not be too broad or too narrow.*

Figure 6.1: Steps of the survey used in this research

Research questions

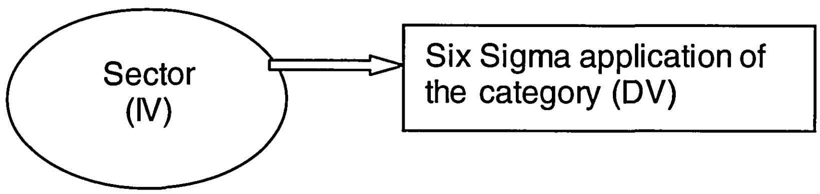


Research questions are derived from the scheme presented in Figure 5.3. The categories number 1 and 2, as already discussed, are taken for granted, but the research at this point wants to investigate whether or not the sector, manufacturing or European Public Health Care, can influence Six sigma application. Therefore, for instance, the category number 3, 'Zero defects and risk management on the caring processes are expected', should be analysed both for manufacturing and European Public Health Care for the purpose of understanding whether there are differences. This applies to each of the categories from number 3 to 10.

6.2.2 Transforming the questions into hypotheses

For each category derived from grounded theory, the question is whether the sector has an influence on the category or not. At this important stage the categories are actually transformed into hypotheses.

Figure 6.2: Sector influence on Six Sigma application



A Chi-square test will be used in order to validate the hypotheses but before proceeding with such a test the null hypothesis has be stated. This latter is the assumption that two variables are independent (Plackett, 1983). After the statement of the null hypothesis, the alternative hypothesis must be stated, and this will be true if the null hypothesis is rejected. Therefore for each category from 3 to 10:

Null hypothesis: *no association exists between the sector and the Six Sigma application of the particular category.*

Alternative hypothesis: *the sector and the Six Sigma application of the particular category are not independent of one another.*

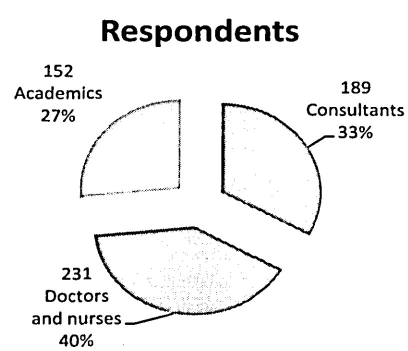
6.2.3 Sampling

One of the most difficult parts of the survey design is the sampling strategy. Sampling is the process in which a fraction of the population is taken. Through statistics the measurement within the sample will be generalised to the population, applying an inference. The reliability of the sample is linked to its size and avoidance of bias.

In simple terms, in statistical concepts the greater the size the greater the precision (Salant and Dillman, 1994). For the purpose of applying a Chi-square test, the researcher must carry out a random selection (Trochim, 2000). Random selection is utilised in probability sampling methods in which the population have equal likelihood of being chosen. In this research the population is given by European Six Sigma experts and the number of people in the sample are the experts that randomly answered to the questionnaire (see next subsection). As Schutt (2006) suggests, the first thing to do in this case is to check that the people meet the criteria for being in the sample, or better for being Six Sigma experts. Consequently, the sample has been formed by practitioners and academics that had already applied or studied Six Sigma for both sectors: manufacturing and Health Care industry. Multi-stage sampling has been chosen as the probability sampling method. This aims to decrease time and cost in sampling and it is particularly suggested when there is not a list of people in the population (in this case a list of Six Sigma experts). In multi-stage sampling the researcher first can select a determined number of clusters at random from the population and then can take a random sample within the clusters (Goldstein, 1995). Hence several clusters have been selected, in particular:

- European consulting firms that have experts in Six Sigma (33%);
- European doctors and nurses who have applied Six Sigma or Lean Six Sigma (40%);
- academics who have been studying Six Sigma and in particular who have got together at a conference or event on the subject (27%).

Figure 6.3: The clusters for the research



In the past 5 years, 572 people have filled in the questionnaire discussed in the next subsection.

6.2.4 Measurement

Quantitative research is based on numbers and therefore the hypotheses discussed below should be operationalised: converting them into numerical data. The instrument used to measure should be evaluated using these criteria (Gall *et al.,* 2003):

- match between the kind of measure and the variable of interest;
- reliability;
- validity;
- cohort appropriateness;
- time and cost;
- ethical issues.

Among the different kind of survey questions the cumulative or 'Guttman scale' has been chosen. The Guttman scale can be used for validating by the means of several statistic tests including Chi square. The Guttman scale ranks how people indicate agreement or disagreement. A series of possible answers creates a sort of uni-dimensional continuum (Guttman, 1950). Because the scale is cumulative this means that the final score is computed by counting the number of answers. In this research, the respondents can choose one of these answers to the questions in the questionnaire:

5 – Strongly agree.
4 – Slightly agree.
3 – Neither agree nor disagree.
2 – Slightly disagree.
1 – Strongly disagree.

Table 6.1 shows the structure and the questions of the questionnaire.

Table 6.1: The categories and the questions for the questionnaire

Category #	Category	Questions
3)	Zero defects and risk management on the caring processes are expected	Do you believe that zero defects and risk management tools are expected in the manufacturing sector? Do you believe that zero defects and risk management tools are expected in the public health care sector?
4)	Six Sigma should be applied across the whole hospital	Do you believe that Six Sigma should be applied in the whole manufacturing organisation? Do you believe that Six Sigma should be applied in the whole public health care organisation?
5)	Statistical tools are better for problem solving inside activities	Do you believe that statistical tools are better for problem solving inside manufacturing activities? Do you believe that statistical tools are better for problem solving inside public health care activities?
6)	Statistical tools in general are less suitable for the Health Care flow	Do you believe that statistical tools are generally more suitable for the manufacturing than other sectors? Do you believe that statistical tools are generally less suitable for the public health care than other sectors?
7	Lean mapping tools (VSM) are more adapted to the whole flow	Do you believe that in the manufacturing sector Lean mapping tools (VSM) are more adapted than other tools for investigating the whole process flow?

		Do you believe that in the public health care Lean mapping tools (VSM) are more adapted than other tools for investigating the whole process flow?
8	DMAIC is always used as a pattern	Do you believe that in the manufacturing sector for Six Sigma projects DMAIC is always used as a pattern? Do you believe that in the public health care for the Six Sigma projects DMAIC is always used as a pattern?
9	No need of Black and Green Belts for short and Lean-based projects	Do you believe that in the manufacturing sector there is no need of Black and Green Belts for short and lean based projects? Do you believe that in the public health care there is no need of Black and Green Belts for short and lean based projects?
10	Climate and rules can affect results	Do you believe that in the manufacturing sector climate and rules can strongly affect Six Sigma projects results? Do you believe that in the public health care climate and rules can strongly affect Six Sigma projects results?

In this way, the respondents are sampled among European experts, the sector is operationalised in two levels, manufacturing and public health care, and five possible answers have been chosen to measure the dependent variable 'Six Sigma application of the category'. A questionnaire based on the last column of

Table 6.1 with seven questions doubled (one for each sector) has been sent to the sample of respondents.

6.2.5 Data collection and statistical data analysis

According to Bryman (2001) there are several ways of delivering questionnaires to respondents. As described in the previous subsection the hypotheses have been transformed into questions inside a questionnaire and operationalised through a Guttman scale. The respondents have been reached by means of email, telephone as well as directly interviewing people. Each interview, self-administered or interviewer administered, is based on a structured interview. Using this approach each interviewee is presented with the same questions in the same order. In this way the answers can be reliably collected, compared and analysed (Bryman, 2001). According to Bryman (2001), Wagner (2007) and Zikmund and Babin (2010), a first appropriate technique for addressing research questions involving relationship with one categorical variable is a frequency distribution or a cross-tabulation. Cross-tabulation is usually a bivariate analysis, an analysis of two variables, one dependent and the other one independent. Using SPSS outputs, section 6.2.5.1.1 shows the relationships between the sectors and the Guttman scale. Chi-square will determine whether a relationship or association between the two variables exists.

In order to evaluate patterns within data, using Microsoft Excel, frequencies of the respondents by clusters, answers (Guttman scale) and questions have been unbundled and shown in the first eight tables in appendix C. According to Bryman (2001), Wagner (2007) and Zikmund and Babin (2010), patterns within tabulations can be analysed using frequencies and percentages. It could be also interesting evaluate percentage change among frequencies, even if these latter and their percentages are fundamental in cross-tabulation. The percentage change has been calculated using the following formula. More generally, if V_1 represents the old value and V_2 the new one, the percentage change is (Bragg, 2012):

$$\frac{\Delta V}{V_1} = \frac{|V_2 - V_1|}{V_1} \bullet 100$$

This formula is not applicable (n.a.) when the denominator is equal to 0. In this case it could be useful to look at the frequencies of the two values.

Reviewing the 572 completed questionnaires it is interesting to note that there are differences in the answers among the three clusters of respondents: consultants, health care professionals and academics. In particular in question 6, concerning association between the sector and the suitability of using statistical tools, the health care professionals differ in the most significant way. As tables 6.2 shows 10 respondents out of 231 (4.33%) answered '5' or 'strongly agree' for the health care question, while 32 out of 231 (13.85%) answered '5' for the manufacturing question; and this corresponds to a 220% increase.

Table 6.2: Question 6 results and comparison between the eight questions by clusters

	Question 6 – Answers for the health care question (association between the sector and the suitability of using statistical tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	0	1	10	52	126	*189*
European doctors and nurses	40	73	56	52	10	*231*
Academics	0	0	6	53	93	*152*
Total	*40*	*74*	*72*	*157*	*229*	*572*

	Question 6 – Answers for the manufacturing question (association between the sector and the suitability of using statistical tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	2	2	13	56	116	*189*
European doctors and nurses	39	70	50	40	32	*231*
Academics	0	0	10	60	82	*152*
Total	*41*	*72*	*73*	*156*	*230*	*572*

European consultants	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	80	49	107	126	88	79	59	140
Manufacturing counting	85	52	107	116	88	80	60	22
Percentage change	6.2	6.1	0	7.9	0	1.3	1.7	#

European doctors and nurses	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	119	130	83	10	102	71	114	163
Manufacturing counting	132	127	81	32	98	71	114	22
Percentage change	10.9	2.3	2.4	220.0	3.9	0	0	#

Academics	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	32	52	40	93	40	80	59	139
Manufacturing counting	30	52	43	82	44	80	59	20
Percentage change	6.2	0	7.5	11.8	10.0	0	0	#

For instance, as discussed in the seventh and eighth chapters, it seems that health care professionals are less accustomed to using statistical tools, consequently they believe that these tools are more suitable for the manufacturing industry. For the same reason, health professionals rated the importance of statistical tools for both sectors much lower than the other groups. This could be an explanation of the strong percentage change in question 6 concerning the 'strongly agree answer' within health care professionals cluster and a lower frequency. However it is very important to notice how the results of the null-hypothesis test for question 6 lead to the conclusion that in the health care as well as in the manufacturing sector to use statistical tools is fundamental.

Reviewing the tables from 9 to 13 in appendix C, it is interesting to notice how the results of the answers have overall minor differences in terms of percentage change. There are two significant changes, 100% and 111.1%, relating to consultants and academics' answers in the tenth and eleventh tables. Neither in the previous qualitative stage, nor in the literature review, is there compelling evidence in order to discuss such figures. Besides in the first case there is just a difference of 1 respondent (1 versus 2). Consequently in terms of frequency cannot be considered relevant.

More interesting, in the ninth table there is an increase of 100% within healthcare professionals relating to question 8. This latter is connected with the use of the DMAIC as a pattern. Consequently it seems that healthcare professionals consider the DMAIC more suitable for health care (10 answers out of 40, 25%) than manufacturing (20 answers out of 40, 50%). Reviewing the findings of the interviews, the focus group and the observations it is difficult to highlight something related to this increase. It could possibly be correlated with the strong level of formality inside Italian public health care organisations where doctors and nurses are well accustomed to strict rules. As discussed in the third chapter, the DMAIC pattern introduces tight rules and roles for the organisation,. In any case this hypothesis cannot be validated neither in a quantitative way nor in a qualitative one and surely needs dedicated research.

Furthermore the results of question 10 are not comparable with the others due to the fact that when answer count is high for manufacturing, the same answer is low for health Care and vice versa. Thence there is a negative correlation as better explained in subsection 6.2.5.1.1.8.

6.2.5.1 Statistical data analysis

The explanatory independent variable 'sector' is categorical, as well as the outcome dependent variable 'Six Sigma application of the category', this latter is broken down into 7 outcomes because the categories taken into account are 7: from number 3 to 10.

A Chi-square test has been used in order to validate the hypotheses. Before proceeding with such a test the null hypothesis has to be stated. This latter is the assumption that two variables are independent (Plackett, 1983). After the statement of the null hypothesis, the alternative hypothesis must be stated and this will be true if the null hypothesis is rejected. Table 6.3 shows the process of hypothesis testing and the null and alternative hypotheses.

Table 6.3: Null and alternative hypotheses

Category #	Null and alternative hypothesis
3	No association exists between the sector and the zero defects and risk management tools application The sector and the zero defects and risk management tools application are not independent of one another
4	No association exists between the sector and the Six Sigma application in the whole organisation The sector and the Six Sigma application in the whole organisation are not independent of one another
5	No association exists between the sector and the use of statistical tools for problem solving inside activities The sector and the use of statistical tools for problem solving inside activities are not independent of one another
6	No association exists between the sector and the suitability of using statistical tools The sector and the suitability of using statistical tools are not independent of one another
7	No association exists between the sector and the use of Lean mapping tools (VSM) for the whole flow The sector and the use of Lean mapping tools (VSM) for the whole flow are not independent of one another
8	No association exists between the sector and the use of DMAIC as a pattern The sector and the use of DMAIC as a pattern are not independent of one another

9	No association exists between the sector and the need of Black and Green Belts for short and lean based projects The sector and the need of Black and Green Belts for short and lean based projects pattern are not independent of one another
10	No association exists between the sector and the possibility that climate and rules could affect the results The sector and the possibility that climate and rules could affect the results are not independent of one another

6.2.5.1.1 Chi-square test report

The Chi-square test has been led using SPSS. The report below shows the results for each answer of the questionnaire and has been divided into three tables. The first one is crosstabulation and it lets you know if a collapse or recoding is needed and what is the observed pattern in the data. The crosstabulations in the columns relate to the answers concerning the questions for the manufacturing sector and in the rows the answers concerning the same question but for Public Health Care. The second table shows the Chi-square results and in particular the 'p-value' or Pearson Chi-square will be taken into account. It is known in statistics that if 'p' is less than 0.05 (5%), the null hypothesis can be rejected and the alternative hypothesis becomes true (Plackett, 1983). Lastly the third table shows the symmetric measures in which in particular the 'Cramer's V' value can be read. The higher the latter is (from 0 to 1) the stronger is the association.

6.2.5.1.1.1 Hypothesis # 3 report

The third hypothesis is about the association between the sector and the zero defects and risk management tools application. The crosstabulation evidence clearly shows that most respondents answered '5' or 'strongly agree' to both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, zero defects and risk management tools inside DMAIC pattern are very important.

The ‘p-value’ of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association between the sector and zero defects and risk management tools application exists. The Cramer’s V statistic takes a high value therefore the association is quite strong.

Table 6.4: Hypothesis # 3, crosstabulation, p and Cramer's V

Question 3* Crosstabulation

Count

		Question 3 manufacturing					Total
		1	2	3	4	5	1
Question 3 Health Care	1	40	0	0	0	0	40
	2	0	44	1	12	17	74
	3	0	0	71	1	0	72
	4	0	0	0	155	0	155
	5	0	0	0	1	230	231
Total		40	44	72	169	247	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1967,070(a)	16	,000
Likelihood Ratio	1392,467	16	,000
Linear-by-Linear Association	455,102	1	,000
N of Valid Cases	572		

a 2 cells (8,0%) have expected count less than 5. The minimum expected count is 2,80.

Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	1,854	,000
	Cramer's V	,927	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.2 Hypothesis # 4 report

The fourth hypothesis is about the association between the sector and the Six Sigma application in the whole organisation. The crosstabulation evidence clearly shows that most respondents answered '5' or 'strongly agree' for both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, the application in the whole organisation is very important. The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association exists. The Cramer's V statistic takes values from 0 to +1 (1 is the strongest association), therefore the association is quite strong.

Table 6.5: Hypothesis # 4, crosstabulation, p and Cramer's V

Question 4* Crosstabulation

Count

		Question 4 Manufacturing					Total
		1	2	3	4	5	1
Question 4 Health Care	1	40	0	0	0	0	40
	2	0	71	1	2	1	75
	3	0	0	70	1	0	71
	4	0	0	0	155	0	155
	5	0	0	0	1	230	231
Total		40	71	71	159	231	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2222,561(a)	16	,000
Likelihood Ratio	1568,453	16	,000
Linear-by-Linear Association	558,938	1	,000
N of Valid Cases	572		

a 4 cells (16,0%) have expected count less than 5. The minimum expected count is 2,80.

Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	1,971	,000
	Cramer's V	,986	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.3 Hypothesis # 5 report

The fifth hypothesis is about the association between the sector and the use of statistical tools for problem solving. Most respondents have answered '5' or 'strongly agree' for both questions. Thus the respondents believe that in both sectors, the use of statistical tools for problem solving is very important. The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Consequently it can be claimed that a significant association exists. The Cramer's V shows a strong association.

Table 6.6: Hypothesis # 5, crosstabulation, p and Cramer's V

Question 5* Crosstabulation

Count

		Question 5 Manufacturing					Total
		1	2	3	4	5	1
Question 5 Health Care	1	39	2	0	0	0	41
	2	0	72	1	0	0	73
	3	0	0	72	1	0	73
	4	0	1	0	153	1	155
	5	0	0	0	0	230	230
Total		39	75	73	154	231	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2201,576(a)	16	,000
Likelihood Ratio	1576,584	16	,000
Linear-by-Linear Association	565,555	1	,000
N of Valid Cases	572		

a 4 cells (12,0%) have expected count less than 5. The minimum expected count is 2,80.

Symmetric Measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	1,962	,000
	Cramer's V	,981	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.4 Hypothesis # 6 report

The sixth hypothesis is about the association between the sector and the suitability of using statistical tools. From the data collected in the qualitative inquiry it seemed that Public Health Care teams were less reluctant to use statistical tools. Once more the crosstabulation evidence clearly shows that most respondents answered '5' or 'strongly agree' for both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, using statistical tools is very important.

The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association exists. The Cramer's V is very high thus the association is quite strong.

Table 6.7: Hypothesis # 6, crosstabulation, p and Cramer's V

Question 6* Crosstabulation

Count

		Question 6 Manufacturing					Total
		1	2	3	4	5	1
Question 6 Health Care	1	40	0	0	0	0	40
	2	1	72	1	0	0	74
	3	0	0	72	0	0	72
	4	0	0	0	155	2	157
	5	0	0	0	1	228	229
Total		41	72	73	156	230	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2232,771(a)	16	,000
Likelihood Ratio	1584,132	16	,000
Linear-by-Linear Association	567,961	1	,000
N of Valid Cases	572		

a 1 cell (4,0%) have expected count less than 5. The minimum expected count is 2,87.

Symmetric Measures

		Value	Approx. Sig.
Nominal by nominal	Phi	1,976	,000
	Cramer's V	,988	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.5 Hypothesis # 7 report

The seventh hypothesis is about the association between the sector and the use of Lean mapping tools (VSM) for the whole flow. The crosstabulation evidence clearly shows that most respondents answered '5' or 'strongly agree' to both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, mapping tools are important for mapping the whole flow.

The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association exists. The Cramer's V is very high thus the association is quite strong.

Table 6.8: Hypothesis # 7, crosstabulation, p and Cramer's V

Question 7* Crosstabulation

Count

		Question 7 manufacturing					Total
		1	2	3	4	5	1
Question 7 Health Care	1	39	1	0	0	0	40
	2	0	74	0	0	0	74
	3	0	0	72	0	0	72
	4	0	0	0	155	1	156
	5	0	0	0	1	229	230
Total		39	75	72	156	230	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2254,023(a)	16	,000
Likelihood Ratio	1602,805	16	,000
Linear-by-Linear Association	569,173	1	,000
N of Valid Cases	572		

a 2 cells (8,0%) have expected count less than 5. The minimum expected count is 2,73.

Symmetric Measures

		Value	Approx. Sig.
Nominal by nominal	Phi	1,985	,000
	Cramer's V	,993	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.6 Hypothesis # 8 report

The eighth hypothesis is about the association between the sector and the use of DMAIC as a pattern. Most respondents answered '5' or 'strongly agree' to both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, the use of DMAIC is taken for granted.

The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association exists. The Cramer's V is nearly 1 thus the association is the strongest.

Table 6.9: Hypothesis # 8, crosstabulation, p and Cramer's V

Question 8* Crosstabulation

Count

		Question 8 manufacturing					Total
		1	2	3	4	5	1
Question 8 Health Care	1	40	0	0	0	0	40
	2	0	74	0	0	0	74
	3	0	0	72	1	0	73
	4	0	0	0	154	1	155
	5	0	0	0	0	230	230
Total		40	74	72	155	231	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2270,398(a)	16	,000
Likelihood Ratio	1614,957	16	,000
Linear-by-Linear Association	569,787	1	,000
N of Valid Cases	572		

a 1 cell (4,0%) have expected count less than 5. The minimum expected count is 2,80.

Symmetric Measures

		Value	Approx. Sig.
Nominale by nominal	Phi	1,992	,000
	Cramer's V	,996	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.7 Hypothesis # 9 report

The ninth hypothesis is about the association between the sector and the need of Black and Green Belts when the Six Sigma project is short or entirely dedicated to Lean. This time the majority of the respondents answered '1' or 'strongly disagree' to both questions. Thus the respondents believe that in both sectors, manufacturing and Public Health Care, there is no need of Black and Green Belts for short projects or projects entirely dedicated to Lean.

The 'p-value' of the Chi-square test is 0.000 hence the null hypothesis can be rejected and the alternative hypothesis accepted. Therefore it can be claimed that a significant association exists. The Cramer's V is nearly 1 thus the association is strong.

Table 6.10: Hypothesis # 9, crosstabulation, p and Cramer's V

Question 9* Crosstabulation Count

		Question 9 manufacturing					Total
		5	4	3	2	1	1
Question 9 Health Care	5	38	0	0	0	0	38
	4	0	78	0	0	0	78
	3	0	0	68	1	0	69
	2	0	0	0	154	1	155
	1	0	0	0	0	232	232
Total		38	78	68	155	233	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2250,211(a)	16	,000
Likelihood Ratio	1598,931	16	,000
Linear-by-Linear Association	558,692	1	,000
N of Valid Cases	572		

a 1 cell (4,0%) have expected count less than 5. The minimum expected count is 2,74.

Symmetric Measures

		Value	Approx. Sig.
Nominale by nominal	Phi	1,986	,000
	Cramer's V	,875	,000
N of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

6.2.5.1.1.8 Hypothesis # 10 report

The tenth hypothesis is about the association between the sector and the possibility that climate and rules could affect the results of a Six Sigma project. Unfortunately the first crosstabulation reported more than 20% of the cells with an expected count less than 5. In this case the Chi-square test cannot be considered valid and there is the necessity of a recoding or collapse. The recoding consists of reducing the number of the answers without making the test meaningless. In this way the recoding has reduced the 5 answers to 3 answers as shown in Table 6.11.

Table 6.11: Recoding for the tenth hypothesis

Strongly agree	5	3	Agree
Slightly agree	4		
Neither agree nor disagree	3	2	Neither agree nor disagree
Slightly disagree	2	1	Disagree
Strongly disagree	1		

As a consequence of the recoding these are the new reports.

Question 10* recoded Crosstabulation

Count

		Question manufacturing			Total
		1	2	3	1
Ques. H.C.	1	16	20	27	63
	2	32	10	25	67
	3	361	69	12	442
Total		409	99	64	572

Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	164,653(a)	4	,000
Likelihood Ratio	142,888	4	,000
Linear-by-Linear Association	146,603	1	,000
N of Valid Cases	572		

a 0 cells (,0%) have expected count less than 5. The minimum expected count is 7,05.

Symmetric Measures

	Value	Approx. Sig.

Nominal by nominal	Phi	,537	,000
	Cramer's V	,379	,000
N. of Valid Cases		572	

a Not assuming the null hypothesis.
b Using the asymptotic standard error assuming the null hypothesis.

The p value is 0.000 hence the null hypothesis is rejected and it can be claimed that organisational climate and rules affect Six Sigma results. However, looking at the crosstabulation there is something very different from the other questions. In this case respondents believe that this is true for Health Care but not for manufacturing. Indeed when the answer number 3, 'agree', is high for manufacturing the same answer is low for Health Care and vice versa.

6.3 Conclusions

This important chapter, in a deductive way, has tested and validated the hypotheses derived from the theoretical preliminary model shaped in the first inductive stage. The results of the literature review, the interviews, a focus group and participant observations have been analysed and categorised through grounded theory. As a result, ten categories linked together can be identified as theoretical principles of the European Public Health Care model. Eight out of ten of these categories have been transformed in this chapter into hypotheses. The first two categories concerning the influence of local authority and the balancing of economic results with other results have been taken for granted and not tested as hypotheses. Indeed from the literature it is well known how important patient satisfaction is and the efforts made by European Public Health Care organisations to improve it. Furthermore, the influence of the local authority and politics on Health Care is a factor issued by the law, especially in Italy. Therefore it does not make sense to test such granted hypotheses. The other eight hypotheses have been tested and apart from the tenth hypothesis it seems that there are no differences from the manufacturing sector. Even the sixth hypothesis regarding the use of statistical tools is considered true in both sectors. However, the tenth hypothesis concerning the influence of organisational climate and rules on the Six Sigma results is considered true only for Public Health Care sectors. The respondents to the questionnaire clearly affirm that in the manufacturing sector there is no influence at all.

These ten validated hypotheses are now the theoretical principles of the European Public Health Care model. To complete the research the new model will be discussed and compared with the manufacturing sector model. The next chapter will try to localise the new model in a philosophical way.
Epistemological and ontological assumptions will be found and compared once more with the similar manufacturing assumptions derived from the literature review.

Chapter 7 – The Six Sigma model for health care

7.1 Introduction

In the fifth chapter, through a grounded theory approach, some categories or theoretical principles were found and linked together. The data gathering for the grounded theory was based on the data and information of two interviews, a focus group, observations and a first literature review. The story line shows how 'The product is the patient' is the core category. Starting from this fundamental principle that represents the Six Sigma European Public Health Care DNA, categories with a stronger relationship with the core were found along with less related categories. Figure 7.1 reveals these important results and tries to link the categories to the core category. In the sixth chapter, eight of the ten categories were transformed into hypotheses and validated using a Chi-square test of association. The 'truth' that arises is underpinned by data and information from a few actors, such as the interviewed doctors and the staff involved in the focus group and in the observation. Therefore, in a original way, the transformed categories have been tested using hypothetical–deductive methods. The first and second hypotheses concerning the influence of the local authority on the Six Sigma results and the balancing of the economic results with other results have been taken for granted and not tested as discussed in the previous chapter.

A questionnaire was sent to academics, practitioners and medical doctors around Europe and answers were compared with the manufacturing sector. As a consequence, the research can finally present a more generalisable model. The conclusions of the hypothesis test in the sixth chapter brought to light some interesting and unexpected results. The most important result is that there are no important differences between the two sectors. Even the sixth hypothesis concerning the use of statistical tools was considered true for Health Care as well as for manufacturing. Only the tenth hypothesis 'Climate and rules can affect Six Sigma results' was considered true for Health Care and not for manufacturing. All the other 6 hypotheses can be considered the same for both sectors. Hypotheses 1, 2 and 10 (see Figure 7.1) are the ones that are different from the manufacturing model. Taking into account these differences, in the following sections the final European Public Health Care Six Sigma model is depicted and the results with the ten epistemological manufacturing assumptions are compared.

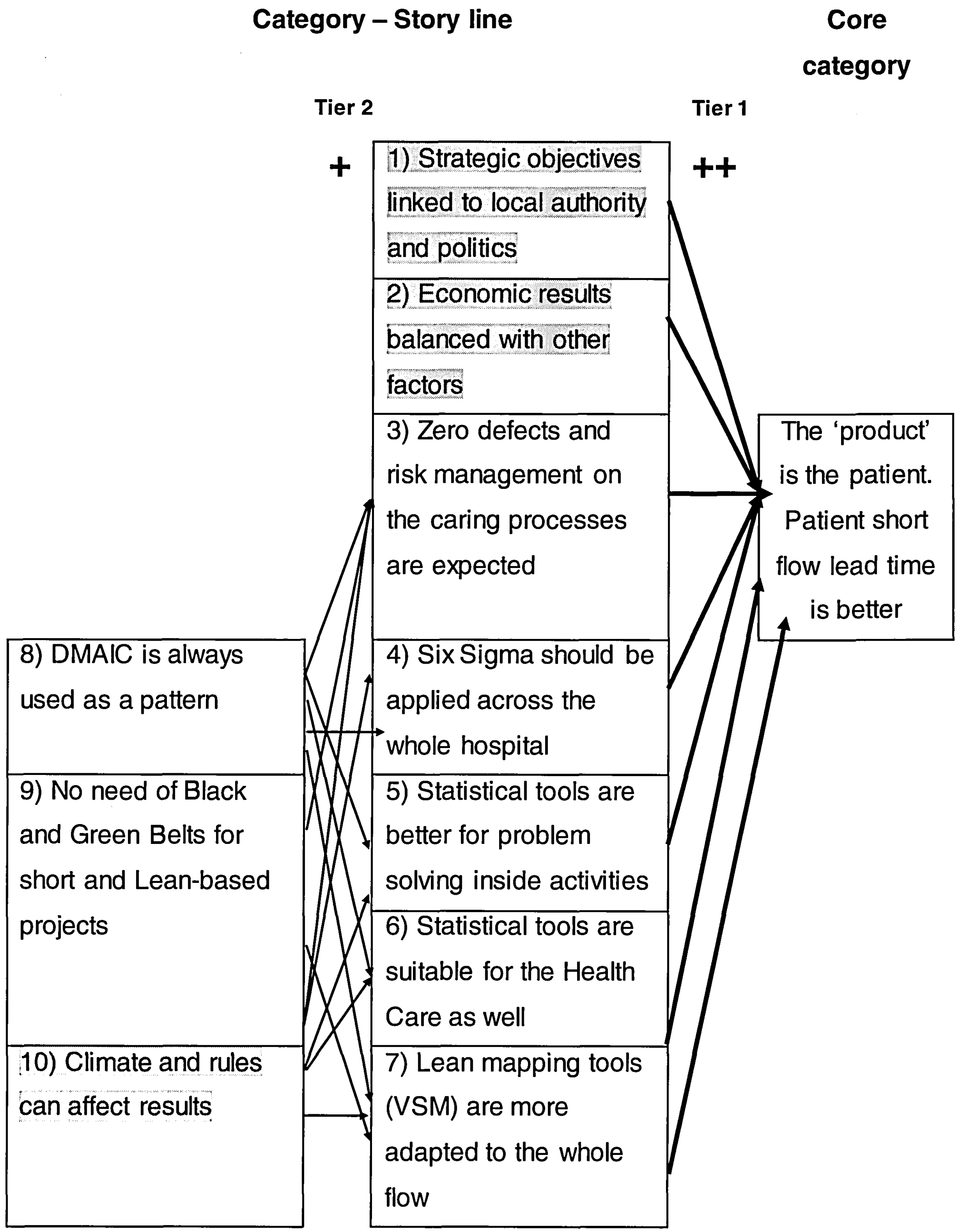
7.2 Shaping the model

In order to better understand what the model for the European Public Health Care sector is, Figure 5.3 has been presented again but in a modified version (see Figure 7.1). The figure has been modified because most of the questionnaire responders consider the sixth hypothesis 'statistical tools are less important for the Health Care sector' to be false.

The model begins with what is the fundamental difference from the manufacturing sector: the kind of processed 'product'. As emerged from grounded theory, the core category in Health Care is the product/the patient and this implies several interesting and 'humanistic' aspects. First, it is well known that in European Public Health Care the patient is a potential voter. Politicians appoint senior managers inside public hospitals in a country such as Italy and Public Health Care receives funds from the public authority as well. Therefore in Italy the local authority is one of the most important stakeholders; it acts as a shareholder and a political authority at the same time. Consequently, it is expected that this public authority issues strategic objectives for Public Health Care as well as balancing economic and patient satisfaction results. It is not unusual to find departments of European hospitals in which patient satisfaction is achieved with increasing budgets (Danielsen *et al.,* 2007). In this way, the first two hypotheses derived from grounded theory have been taken for granted and they have not been validated by means of quantitative methods. In any case the model as a whole cannot be interpreted without these expectable founded differences.

In the next subsections all the hypotheses will be discussed and compared with the ten epistemological assumptions found for manufacturing sector.

Figure 7.1: The story line and relationships among the theoretical principles (categories) – the final model



7.2.1 Zero defects and risk management on the processes

Six Sigma is a very powerful management system used to reduce defects and consequently errors into processes (Harry and Schroeder, 2000). DPMO is more than a motto and, as seen in the third chapter, at the end of the improvement projects, teams have to certify the strict results in terms of saving and COPQ reduction. Therefore, both manufacturing and Health Care industries have to reach zero defects. In the manufacturing sector, zero defects can sometimes be something reasonable whereas in Health Care zero defects must not be reasonable but proved. The greater the risk the less are the expected defects and Health care, like the aerospace and nuclear industries, must be intrinsically at zero defect. A surgery process cannot fail and consequently all the tools to avoid errors must be used. Risk management and risk analysis are at the base of all the DMAIC stages, starting from the definition of the kind of risk for the patient, its measure, cause analysis of the risk and the inevitable improvement and control. Tolls such as FMEA or FTA are of vital importance (DeRosier *et al.*, 2002) and in order to avoid any kind of risk, mistake-proofing tools are mandatory. These latter are tools for eliminating human error such as computerised and automated systems for associating patients and their drugs or robotic surgery. Control plans as well must be very rigorous with the scope of detecting any cause of risk for the patient. Thus, ultimately, it can be claimed that zero defect and risk management are the most important drivers within the DMAIC pattern.

7.2.2 Six Sigma should be applied in the whole hospital

This hypothesis was largely confirmed and brings an important discussion that is present in the manufacturing sector as well. Six Sigma is expected to be applied in the whole organisation otherwise there can be failures (Goh, 2002). Six Sigma passes through a long-term cultural change programme without end as 'being excellent' requires. However, being excellent also requires a complete application of Six Sigma because processes are cross-department inside a hospital. Unfortunately, senior managers tend to apply Six Sigma in a few departments; this is mostly due to the complexity of Six Sigma and management involvement. In this way there are some differences between Health Care and manufacturing. In the manufacturing sector, senior managers, CEOs and general managers can usually move the whole organisation easily towards Six Sigma. In the third chapter they have been called 'Visionary top managers' and they can issue strategic objectives within the business plan and act as sponsors. In European Public Health Care a General Manager for instance is supposed to negotiate strategic objectives with politicians as well as with all the department heads. As previously discussed, department heads inside European Public Health Care have a strong organisational power and they can sometimes even launch out into Six Sigma without involvement of the General Manager. It is rare but it can happen that they can also stop Six Sigma implementation within their departments.

7.2.3 Statistical tools are better for problem solving inside process activities

In both the industries statistical tools are considered more suitable for problem solving inside process activities. As George argued (2002), Six Sigma and its original statistical tools are very powerful for reducing variability inside processes. This means that if the scope is to find the root causes of a problem or defect, then statistical tools such as DOE, ANOVA, regressions and many others are the most suitable. Indeed they can relate causes and effects in a mathematical way and validate the solutions. Statistical tools are especially used when problems are directly linked to severe risks for patient, whereas more qualitative and managerial tools are less used or just used for a first approach.

7.2.4 Statistical tools are suitable for Health Care as well

In the fifth chapter it emerged, by means of grounded theory, that European Public Health Care is not oriented to using statistical tools. This is mostly due to the background of medical doctors and nurses: doctors and nurses are usually taught less statistics and mathematics than engineers and other kind of professionals and they use statistical tools less than manufacturing managers. It is therefore more difficult to involve Health Care staff in training concerning statistical and advanced statistical tools. However, this typical situation inside Public European Health Care does not do as an excuse for not implementing statistical tools inside the DMAIC pattern. According to the result of the hypothesis test in the sixth chapter, statistical tools in Health Care are as suitable as in the manufacturing sector. European Health Care doctors and nurses are supposed to learn and carry out DMAIC improvement projects even if statistics is something new.

7.2.5 Lean mapping tools are more suitable for the whole flow

If statistical tools are more suitable for problem solving and for finding root causes inside activities when Six Sigma teams manage an entire process or better a process flow, then tools borrowed from Lean Thinking can be more useful. This is especially so at the beginning of the Six Sigma journey when teams have to map the whole flow, for instance from the emergency to the surgical unit. Processes inside a flow are linked together and performance improvements are reached when all the processes work in unison. Six Sigma teams can better identify where the wastes and problems are and how to manage them by mapping the whole patient flow. In addition, because shorter patient flows are better, by using mapping tools the team can measure and improve the whole lead time. In this way VSM or other mapping tools borrowed from Lean such as Makigami are more suitable. As shown in the third chapter these tools can help teams to see within processes and identify problems that then should be improved by the DMAIC pattern.

7.2.6 DMAIC is always used as a pattern

Since the 1990s Six Sigma has been synonymous with DMAIC. The DMAIC pattern is perhaps the most important part of Six Sigma DNA (Byrne and Norris, 2003) in Health Care as well. The hypothesis test in the sixth chapter validated the hypothesis that DMAIC is always used in both Health Care and manufacturing. Every stage of DMAIC, from Define to Control, allows doctors and nurses to improve patient satisfaction as well as reduce any kind of risk or cutting of costs. Within the DMAIC pattern, as shown in previous sections, teams can use all the tools but risk management tools are the most important for Health Care.

7.2.7 No need of Black and Green Belts for short and Lean-based projects

As discussed in the third chapter, Lean Thinking is mainly carried out by means of Kaizen events (Alukal and Manos, 2006; Manos, 2007; Dickson *et al.,* 2009).

The peculiarity of these improvement projects is the short duration (on average a week). The results of the hypothesis test clearly show that there is no need of Black and Green Belts inside Kaizen events. This is quite predictable because a Kaizen event is something that purely belongs to the Lean world in which tools such as 5S, SMED, Kanban and many others are very focused on lead time reduction. Before Six Sigma encountered Lean, there was no reason to use DMAIC pattern for Lean projects and also nowadays a pure Lean event does not need this pattern. As claimed several times, Lean lent its tools to Six Sigma and not vice versa and the DMAIC rigour seems to be better for longer and more structured projects than a Kaizen week. Additional research could be done in order to understand whether a Green or black Belt can be involved in Lean teams and in what circumstances.

7.2.8 Climate and rules can affect results

This last hypothesis is surely one of the most important. Organisational climate and strict rules seem able to affect results in European Public Health Care. This hypothesis has been validated in the previous chapter for Health Care but not for the manufacturing sector. What are the reasons and the differences between the two sectors? As discussed in the third chapter, the differences are not only based on financial and economic matters. Piko (2006), for example, studied the relationship among burnout, role conflict and job satisfaction. As a result he found that role conflict is a factor that can affect team efforts. Kob and Finzi (2009) analysed possible conflicts between the Hospital Director and Head of Departments. The conflicts are due to the fact that Hospital Directors are sometimes sort of politicians and act differently from Head of Departments. In addition this latter, sometimes, are so powerful that they can create obstacles for projects launched by top managers. Last, but not least, there are conflicts between doctors and nurses especially about care roles and once more conflicts can affect results of improvement teams.

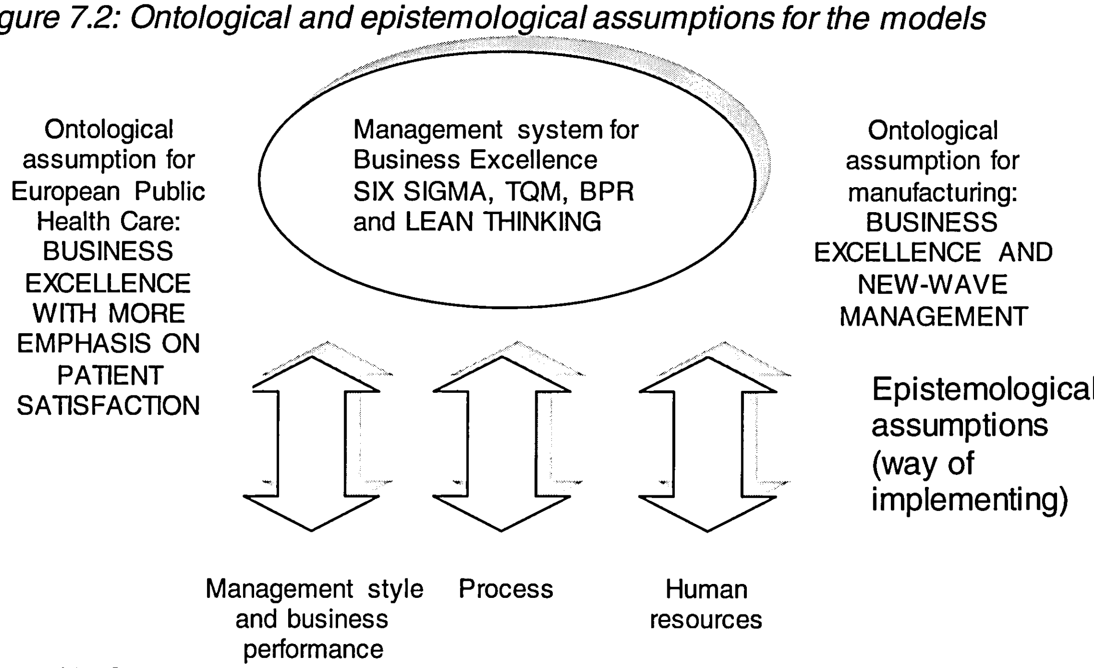
A hypothesis test rejecting the same situation could happen in the manufacturing sector. Even though it is not the scope of this PhD research, the reasons can be briefly explained. Managers inside manufacturing companies, particularly worldwide companies, are generally more aligned on values and strategies than Public Administrators (Parker and Bradley, 2000). If the top management issues precise Six Sigma objectives, and the vision of the company becomes Six Sigma, it is difficult for managers to obstruct such a course. Managers inside worldwide companies can be chosen and even laid off on the basis of their attitudes and skills in order to carry out strategic objectives (Szilagyi and Schweiger, 1984). The company must be a perfect clockwork in a post-Fordist economy (Belassi, 2000); the Tayloristic approach is finished, managers are involved in different ways but all managers must reach agreed targets. Consequently, managers have more degrees of freedom about appointing team members and managing them. Organisational climate, rules, roles and responsibilities become something of a modifiable expendable for reaching Six Sigma objectives. Six Sigma projects can be slowed down but sooner or later any kind of obstacle will be removed including top managers.

By contrast, European Public Administration, including Public Health Care as discussed in the third chapter, presented political constraints, strong power of Department Heads, difficulties in changing job descriptions, strict roles and responsibilities as well as intrusions of the trade union into decision making. In an interesting article, Amalberti *et al.* (2005) discussed five system barriers to achieve ultra-safe Health Care in the USA. Ultra safe Health Care or expected zero defects is one of the most important hypotheses previously analysed inside the model; it is mandatory. According to Amalberti *et al.*, sometimes the zero defect target cannot be achieved because of the discretion of doctors and nurses or professional autonomy. It is a sort of paradox because professional rules and regulations are very strict but at the same time Health Care staff sometimes have too much discretion; this latter situation is particularly true in European Public Health Care. In addition, in countries such as France, Germany, Italy and Spain, trade unions are fundamental to decision making even if they have been losing members in the last decade. Therefore it is quite difficult to change job descriptions and rules or responsibilities inside European Public Health Care because trade unions and local contracts do not easily permit it.

7.3 A philosophical comparison between Six Sigma for manufacturing and European Public Health Care industries

In the third chapter a comparison among Six Sigma, TQM, BPR and Lean Thinking was made. The comparison highlights how Six Sigma and the other management systems are ontologically based on the Business Excellence assumption. Six Sigma in the manufacturing sector leads an organisation towards excellence by means of continuous improvement, cost reduction, customer satisfaction and a process approach. Ontologically, Six Sigma for manufacturing is a basic category of being (Haach, 1978) within 'excellence' and epistemology is the way of knowing or implementing Six Sigma towards excellence. Thus in the third chapter ten epistemological assumptions for Six Sigma in manufacturing were found through a literature review. The ten epistemological assumptions represent rational and impersonal processes for achieving Business Excellence implementing Six Sigma. However, are there ontologically any differences between being excellent in manufacturing and in European Public Health Care? Looking at the results from grounded theory and hypothesis test validation it seems that ontologically the basic category of being excellent in Health Care is slightly different from manufacturing.

Figure 7.2: Ontological and epistemological assumptions for the models



In Health Care, business excellence is also something measur
continuous improvement, cost reduction, customer satisfaction and a process approach. However, customer or better patient satisfaction acquires a different

and stronger emphasis. Patient satisfaction almost coincides with business excellence and in its name sometimes all the other aspects can be sacrificed.

Manufacturing assumptions	European Public Health Care assumptions

7.3.1 Comparison of Six Sigma epistemological assumptions

In the third chapter after a literature review, ten epistemological assumptions have been found and categorised into three dimensions:

- Management style and business performance – how top and senior managers define their strategy and develop it into organisation processes; what the expected results are.
- Processes – what kind of tools the management system uses, patterns and specific paths for the projects, skills and rules.
- Human resources – how employees are involved and what kind of skills they need.

Table 7.1 sums up the ten epistemological assumptions.
According to the hypotheses tested in the previous chapter and presented in the above sections, the ten epistemological pillars can be reread and modified on the basis of European Public Health Care principles. In the next sections they will be compared with manufacturing principles. Ten epistemological assumptions will represent the way of implementing the European Public Health Care Six Sigma model. Table 7.3 sums up the results of the comparison between manufacturing and European Public Health Care organisations.

Improves business performance in general, cost reduction model particularly concerning COPQ	Improves quality performance, particularly COPQ, cost reduction is sometimes inevitably balanced with patient satisfaction
Requires visionary top management. High commitment and involvement	Requires top management high commitment and involvement. Political influences
Reduces variation within the processes. Certified results	Reduces variation within the processes. Zero defects and reduced risk for health of patient as a result
Requires focus and capture of the voice of the customer. Definition of critical characteristics for products	Requires focus and capture of the voice of the customer. Definition of critical characteristic for patient
Focuses on improving processes of the whole organisation through DMAIC approach	Focuses on improving processes of the whole organisation through DMAIC approach. Risk of application in few departments because of obstacles inside senior management
Uses of all kind of tools derived from quality and other management systems	Uses of all kind of tools derived from quality and other management systems. Lean tools important for mapping patient flow and reducing lead times
Short- and medium-term improvement project but long-term cultural change	Short- and medium-term improvement project but long-term cultural change. Politics, trade unions and strict roles and responsibilities do not help to reach this radical change
Involvement of employees. Team oriented and use of certified Black and Green Belts	Involvement of employees. Team oriented and use of certified Black and Green Belts
Also requires skills based on statistics and data	Also requires skills based on statistics and data, even if statistics is not the background of doctors and nurses
Self-empowerment and responsibility	Self-empowerment and responsibility. Failure risks due to strict roles and responsibilities

Table 7.1: Epistemological assumptions in manufacturing and Health Care

7.3.1.1 The first assumption: Six Sigma improves business performance particularly patient satisfaction

As discussed in Section 3.5.2.1, since the first papers in the 1990s dedicated to Six Sigma, practitioners and academics have dealt with the cost reduction objective. In the manufacturing sector it can be claimed that Six Sigma leads mainly to COPQ reduction. The DPMO concept is an important way to measure how successfully Six Sigma is implemented and this is also confirmed for the Health Care sector. The only difference, as already discussed, is that the Six Sigma Health Care model is not as focused as the manufacturing one on cost reduction. Cost reduction is sometimes inevitably balanced with patient satisfaction.

Table 7.2: Six Sigma epistemological pillars for the manufacturing sector

Dimension	Epistemological assumption
Management style and business performance	11) Improves the business performance in general, cost reduction model particularly concerning COPQ 12) Requires visionary top management. High commitment and involvement
Processes	13) Reduces variation within the processes 14) Requires focus and capture of the voice of the customer 15) Focuses on improving processes of the whole organisation through DMAIC approach 16) Uses of all kind of tools derived from quality and other management systems 17) Short- and medium-term improvement project but long-term cultural change
Human resources	18) Involvement of employees. Team oriented and use of certified Black and Green Belts 19) Requires skills based on statistics and data 20) Self-empowerment and responsibility

In the manufacturing sector it can be found that Six Sigma projects can be dedicated not only to product quality. There are applications for instance into supply chain management, information security management, environmental management systems and in many other sectors. In the third chapter the review of Six Sigma Health Care literature showed that there is a lack of similar projects. Six Sigma for Health Care seems to be, at present, very focused on quality and risk management.

7.3.1.2 The second assumption: top and senior management involved, political influences

In both sectors, manufacturing and Health Care, Six Sigma is a long-term journey and it has a specific deployment starting from the top management. Inside top management a 'sponsor' and a 'champion' are supposed to manage the organisation as a whole towards Six Sigma. In manufacturing, without a clear and well-noticed top management, commitment to Six Sigma can fail. In European Public Health Care the situation is quite similar but, as previously discussed, top management can sometimes come into conflict with senior managers especially powerful Head of Departments. In manufacturing, leadership and strategic management for Six Sigma should be visionary because culture and charisma can easily move strategies into processes. In European Public Health Care this is not quite true. A visionary top manager should agree his/her vision with the local politicians. In addition, because of the strict rules, responsibilities and trade union power, his/her charisma has less influence on staff.

7.3.1.3 The third assumption: Six Sigma reduces variation within the processes

Literature and hypotheses tested agree that in both sectors Six Sigma is very problem-solving oriented and the DMAIC projects should reduce variation within the processes. Reducing variation around the expected target of each process leads to reduced risks for the patient and to the zero-defect principle. Every Six Sigma improvement project in Health Care is a challenge in pursuit of the root causes of patient health risks. To analyse and identify root causes the Health Care Six Sigma teams have to use advanced statistical tools despite their medical background.

7.3.1.4 The fourth assumption: Six Sigma requires focus and capture of the voice of the customer

In the manufacturing sector the principle of 'external errors cost' has been discussed: the cost incurred because the output did not meet customer expectations. A manufacturing company can suffer costs such as warranty costs, returned goods, penalties and even customer loss; consequently Six Sigma is focused on capturing 'spoken', 'unspoken' and 'delightful expectations' (Kano, 1984). Inside spoken and unspoken expectations Health Care organisations are particularly careful about risks for patients such as infections, diagnostic and therapy errors, discharge time and many others.

7.3.1.5 The fifth assumption: Six Sigma focuses on improving processes of the whole organisation through DMAIC approach

As discussed in Section 7.2.2 Six Sigma should be performed within the entire organisation through the DMAIC pattern. To simplify the approach, manufacturing and Health Care organisations sometimes launch Six Sigma in a few departments or processes (Pande *et al.,* 2000). As deeply analysed, such an implementation could cause many problems because processes are linked together and performance improvements are reached through the value stream flow. An emergency department, for instance, can reduce waiting list time only if the laboratory or the X-ray unit do not slow down their flow. Unfortunately, in European Public Health Care there are several obstacles such as different departments with different senior managers, strict rules and responsibilities and many other aspects that can reduce the implementation spread.

7.3.1.6 The sixth assumption: Six Sigma uses all kind of tools derived from quality and Lean

Six Sigma in Health Care inherits different tools from TQM and Lean Thinking. At the beginning, improvement teams should map the entire patient flow using VSM. VSM is a power tool that can discover all kind of wastes and problems and show the track to follow using the DMAIC pattern. VSM is surely one of the most important tools borrowed from Lean Thinking that is largely applied in Health Care and manufacturing (Proudlove *et al.,* 2008). Within the DMAIC pattern, Six Sigma teams can use numerous tools dependent on the scope and the kind of stage. In the Define stage, Six Sigma teams have to capture the voice of the patient and understand firstly where and what the risks are for the patient. In this first stage, teams have to state what the CTQs are for the patient and in this way start risk management. In the Measure and Analyse stages all the TQM tools are used in order to identify the root causes of variation. In the improvement stage, Six Sigma teams can use both TQM and Lean tools depending on the scope. If the target is to reduce lead time inside processes, then Lean tools are surely more suitable than other tools. Table 7.2 summarises the scope of Lean tools inside the different DMAIC stages.

Table 7.3: Lean Thinking tools and their use inside DMAIC pattern for Health Care

Lean Thinking tool	**Scope of the tool**	**DMAIC stage**
VSM	Mapping the flow of the patient to seek for waste	Define, Analyse
Makigami – Lean Office	Mapping the flow of data/information instead of something physical. Particularly used in Lean Office and for transactional processes. Used for finding the non-value added activities	Define, Analyse
5S	Five very simple steps for setting in order and cleaning up the workspace. In Health Care it increases productivity as well as reduces infections	Improve
One-Piece-Flow	Processing different kind of therapies or diagnostics one at a time avoiding queues of patients	Improve
SMED – Quick Changeover	It reduces the set-up times for medical machines and organisational systems such as operating rooms	Improve
Kanban	A specific card that signals the need of a product or a service. It is particularly used to reorder drugs and disposables	Improve
TPM	A system for introducing preventive maintenance of the medical machines and equipment and raising the awareness of the workers about self-maintenance. TPM reduces machine down-times	Improve
Poka-yoke, mistake proofing	A tool for avoiding human errors on the processes, reducing the defects and the risk for the patient (e.g. drug preparation and administration or surgical errors)	Improve

It can be claimed that the tools are the same as those of the manufacturing sector even though tools that reduce risks for patient health are preferred.

7.3.1.7 The seventh assumption: short- and medium-term improvement projects but long-term cultural change

This assumption can be considered quite similar for both sectors. Six Sigma projects take on average from a few months to one year and thus their yield is short- and medium-term based. However, like the other management systems that lead towards business excellence, Six Sigma passes through a long-term cultural change programme without an end. This is an indisputable assumption; unfortunately European Public Health Care is not the best kind of organisation for long-term cultural change. Politics, trade unions and strict roles and responsibilities do not help to reach this radical change.

7.3.1.8 The eighth assumption: involvement of the employees. Team oriented and use of certified Black and Green Belts

Management commitment and involvement is a fundamental pillar especially concerning top and senior management. In any case, the entire organisation must be involved including doctors and nurses. Linderman *et al.* (2003) dealt with the aspect that Six Sigma organisations should train all employees by extensive programmes. The subjects are both technical and managerial; indeed teamwork is a fundamental Six Sigma principle (Coronado and Antony, 2002). Therefore at this level Six Sigma uses important tools such as team building and team efforts and each Six Sigma team leader (i.e. Black and Green Belt) is supposed to be trained in these subjects not only on statistics matters. Black and Green Belts should be certified through a precise and well-coded training (Harry and Schroeder, 2000). According to the results of the hypothesis test, teams do not need contributions from Black and Green Belts in the cases of pure Lean projects and very short projects.

7.3.1.9 The ninth assumption: Six Sigma also requires skills based on statistics and data

Hahn *et al.* (2000) in their discussion about statistics training referred to a 'democratisation of statistics' within Six Sigma. Instead the results of the interviews in the fourth and fifth chapter show how reluctant doctors and nurses are to be involved in statistics training. In fact, the hypothesis test presents a different outcome because people that answered the questionnaire believe that statistical tools are suitable for both sectors. Therefore every Health Care employee should be trained at the requested level for his/her role on statistics.

Six Sigma also has a strong approach based on facts and data. All the project results are validated using 'sigma level' around the target. In the manufacturing sector the finance department is sometimes assigned to calculate and report savings achieved to senior management; this happens in the last control stage of the DMAIC pattern. In Health Care in the last stage the teams have always to take into account risk reduction for the patient.

7.3.1.10 The tenth assumption: self-empowerment and responsibility

Employees within Six Sigma teams should act their roles with self-empowerment and responsibility. Each participant within Six Sigma projects is controlled by a Black or Green belt but participants are supposed to take on responsibility about rules and scheduling.

Strict rules and responsibility in the European Public Health Care sector can cause difficulties in choosing the best employees for Six Sigma projects. Once a manager has identified the right people, they are usually strictly tied to their job descriptions and contracts and thus it is more difficult than in the manufacturing sector to establish a team.

7.3.2 New-wave management for European Public Health Care

In the third chapter it emerged that Six Sigma can be considered an example of New-wave management. Organisations in European Public Health Care also want to implement Six Sigma to try to follow the typical strategies of New-wave management. According to McAuley *et al.* (2007, p. 150) these latter are:

- *creating and communicating a shared vision*
- *creating flatter less hierarchical organisations,*
- *generating flexibility and freedom by giving employees autonomy through empowering them,*
- *promoting entrepreneurship and risk taking amongst managers based upon their reading of the environment and anticipating change,*
- *developing skills of remote management so that management control may be exerted from a distance,*

- *building flexible organisations around small groups or teams.*

However, in the European Public Health Care sector it seems more difficult to aim for such strategies. Vision, for instance, in a country such as Italy can quickly change because of political issues, therefore is not so easy to create and share a stable one. Furthermore, creating flatter organisations and generating flexibility within employees' actions is rather difficult because of the doctor and nurse contracts, their backgrounds and the organisational climate, as better discussed in the next chapter. In a nutshell, a European Public Health Care organisation that wants to apply Six Sigma shall struggle between the deployment of the New-wave management strategies and a formal organisational control similar to a bureaucratic one (Heckscher and Donnellon, 1994).

Table 7.4 summarises the differences between manufacturing and the Public Health Care sector related to types of organisational control.

Paradoxically, Table 7.3 shows how bureaucratic control is as strong as informal control. This can be explained as a reaction to bureaucratic control. For instance doctors and nurses often have predetermined roles and precise hierarchical positions that can be discussed inside a Six Sigma team. This sometimes happens in an informal way without changing the job description or involving the senior managers.

7.4 Conclusions and next steps

This chapter has presented the model for European Public Health Care. Ten theoretical principles are, on the basis of this model, linked together and with

Table 7.4: Different types of organisational control

	Bureaucratic control	**Output control**	**Cultural control**	**Informal control**
Manufacturing sector	*Weak.* Rules and roles quickly change with the objectives	*Strong.* Results are always measured and certified	*Strong.* Emphasis on a development and	*Weak.* Official rules and roles are dominant

	and targets		maintenance of a shared culture	
European Public Health Care sector	*Strong.* Rules and roles are fixed by contracts, cultural background and even politics	*Strong.* Results are always measured and certified	*Weak.* It is difficult to harmonise different cultural issues inside departments	*Strong.* Unofficial rules and practices turn up as a reaction to bureaucratic control

the core category. Furthermore, ten epistemological assumptions or way of implementing the model have been compared with the similar manufacturing assumptions. The core category 'The patient is the product' has been considered part of the ontological assumption of the model within the discussed excellence. Three out of ten of the theoretical principles are different from those of the manufacturing sector: the influence of the local authority on Six Sigma objectives, the balancing of economic results with patient satisfaction aspects and the influence of organisational climate on Six Sigma results. The influence of the local authority is a factor particularly linked to the Italian National Health Care system and is therefore not so generalisable to all Europe. The other theoretical principles are similar to those of the manufacturing sector as the hypothesis test demonstrated in the sixth chapter. In any case, Six Sigma for European Public Health Care seems to have more emphasis both on formal control such as bureaucratic control and informal control. However, reviewing the results of the inductive–qualitative stage some 'thin' aspects can refine the theoretical principles in order to better understand the model. This is considered a triangulation between qualitative and quantitative methods.
The next chapter will better investigate the found differences between the two models dividing the differences into more and less significant.

Chapter 8 – Understanding the differences

8.1 Introduction

In the seventh chapter, using the grounded theory results, the final Six Sigma model for the European Public Health Care sector was shaped. Furthermore, in the sixth chapter, the grounded theory categories that were transformed into hypotheses have been tested by the means of a Chi-square test. As a result, the model presented in Figure 7.1 shows in general the important theoretical principles on which Six Sigma for European Public Health Care is underpinned. The principles as a whole represent the generalisable theory or the final model that the research aimed to reach. In addition, in the seventh chapter the tested grounded theory categories have been used for rereading and comparison with the ten manufacturing epistemological assumptions. These latter are the way of implementing Six Sigma that were found and depicted for the manufacturing sector by a deep literature review in the third chapter.

In the end, the discussion about the principles has clearly enlightened how some of them in the Health Care sector can differ from the same manufacturing categories. Every principle has differences with respect to the manufacturing model and these differences can be slight or very important. The differences in their own generality were discussed in the seventh chapter but at this point the research needs to better analyse, discuss and especially prioritise such differences. For this final analysis the qualitative method results will be useful to better understand details that the final model cannot, because of its nature, show.

8.2 Triangulation for a deeper discussion

The research methodology was presented in the fourth chapter. It is divided into a first inductive stage based on qualitative methods along with grounded theory and a second stage entirely based on quantitative methods. The tested hypotheses have depicted the model discussed in the seventh chapter. At this point it is important to understand the differences between the two models and seek more details about the involved organisations through the results of qualitative inquiry. Qualitative research is effective in discovering cultural elements regarding behaviours, social and political context, values and organisational climate (Denzin, 2000). For instance, Italian Public Health Care has important differences from other European countries. When used along with quantitative methods, in the triangulation, qualitative inquiry helps to better interpret a proposed model and the possible consequences of quantitative results.

8.3 What is significantly different?

Reviewing the results presented in the seventh chapter in terms of theoretical principles and epistemological assumptions, the research can now highlight and discuss the major differences with respect to the traditional manufacturing Six Sigma model. Other minor differences come out from the results of the interviews and the focus group and are considered more disputable but are taken into account in the next subsections. Table 8.1 sums up what these differences are and which are the more significant compared with the manufacturing model.

The theoretical principles that do not offer any difference from the manufacturing model are not obviously discussed. In any case these principles are well known and discussed in classic manufacturing Six Sigma literature. Further details can be found in the second and third chapters.

8.3.1 The influence of politics on Six Sigma strategic objectives

The Public Health Care system is different within each European Country. The European Union (EU) is following the precise goal of leaving its member countries free to organise their own National Health Care system. The Treaty of Lisbon (EU, 2010) legitimates that each EU member has the exclusive right to organise its National Health Care services. In this way each country can autonomously decide how to establish and control the Health Care budget. As a

Table 8.1: Differences from the traditional manufacturing Six Sigma model

Theoretical principle	Difference
Strategic objectives can be linked to politics,	High

particularly to local authority in some European countries such as Italy	
Economic results must be balanced with other factors	High
Climate and rules in Health Care can affect results more than in the manufacturing	High
'Zero defects' is expected. Risk management tools are slightly more important than other tools	Medium
Advanced statistical tools are used less in Health Care	Low
Complex Health Care organisations should be managed as a whole	Low

consequence, nowadays in the EU there are two different and important Health Care systems at the same time (Van Der Zee and Kroneman, 2007).

The German Chancellor Otto Von Bismarck established the first at the end of the nineteenth century and it is based on a tax directly applied on salaries. This tax is a sort of mandatory insurance and different payers including employees and employers finance the Health Care system. This system implies that the government is just a regulator even if it can finance the systems. The total expenditure on health is formed by the social insurance and government funds. The politics, in this way, is far from interfering in the strategies of a single public hospital. Countries such as Austria, France, Germany and Luxembourg have inherited this system. In past years Holland has implemented a particular evolution of Bismarck's system in which citizens can choose between private and public Health Care services and at the same time can choose to which of the two to give their money.

Lord Beveridge established the second important system in 1942. This system is based on the concept of the government as a single payer. Lord Beveridge did not think about the possibility of Health Care services being run by the private sector. The central government pays for, controls and provides Health Care services. Countries such as Sweden, Denmark, Finland, UK, Greece, Ireland, Norway and Portugal have inherited this system. Italy is the only country that changed its system from a Bismarck's system to a Beveridge's one in the 1960s. Politicians are accountable to citizens for the results achieved by the Public Health Care organisations in terms of patient satisfaction. In this way politicians and their laws affect the strategic objectives of Health Care organisations but without going into details such as what kind of management system could be the best. Public Health Care general managers are almost free to decide their own strategies.

8.3.1.1 The Italian case

In 1968 Italy changed its National Health System (Italian Official Journal, 1968) transforming its hospitals and hospital services into Public Administrations. In 1974 another fundamental law (Italian Official Journal, 1974) shifted the administration and control, including the economical–financial aspects, from the central government to the Regions. Italy is divided into 20 Regions; each one has a specific Health Care Department that decides the most significant aspects of Health Care management. For instance, these Departments issue the guidelines for the accreditation of the organisations, both private and public. In addition, they evaluate the quality of the provided service and the dedicated infrastructures.

But how do the Regional Health Care Departments affect strategic objectives including Six Sigma objectives? First of all, they can strongly interfere with the choice of a management system. For example, since the 1990s several Italian Regions have imposed on Public Health Care the adoption of ISO 9001 requirements and in Regions such as Trentino Alto Adige, Veneto and Tuscany there has been experimentation with the EFQM model. Since 2004 Lombardy has forced its Public Health Care organisations towards the implementation of the American Joint Commission on Accreditation of Health Care Organizations Model. This latter is considered a management system for the so quoted and discussed in the third chapter 'excellence' (Snyder, 1997). Furthermore it is interesting how Tuscany is experimenting with the Lean Thinking approach in a few Hospitals. Both have also been using Six Sigma tools and principles inside the improvement projects. These are the organisations in which the interviews, a focus group and the participant observation were held. In this way a Regional Health Care Department strongly affects strategic objectives inside Public Health Care organisations concerning quality, costs, services, safety and environmental matters and many others.

However, each of these Regional Health Care Departments has a chief in charge who is a local politician and he or she sometimes takes his or her decisions based on the local election. In addition, quite a few Hospital General Managers are appointed by the local politicians, often unfortunately with little Health Care skills or even worse with no managerial skills at all. According to a survey carried out by the University of Milan 'Luigi Bocconi' and Censis (Censis *et al.,* 2009), just 33.3% of Italian General Managers inside public hospitals have got a Health Care background and 44% of them in South Italy have a pure political background. The General Managers appoint many Heads of Departments and doctors inside the hospitals. However, a General Manager is subject to the 'caprices' of the local politicians and as a consequence of that he or she normally holds this position on average for two or three years. The Heads of Departments and the doctors in Italy cannot be fired and thus, sooner or later, they have to compare their objectives with the ones of a new General Manager appointed by new local politicians. This situation can also affect the relationship between senior managers inside Public Health Care organisations. The organisational climate tends to negatively influence Six Sigma project results. The results of the focus group discussed in the fifth chapter show how doctors and nurses believe that sometimes Six Sigma can be a fad just introduced by a new General Manager.

8.3.2 Balancing economic results with the other important objectives

Citizens of all European countries consider Public Health Care services as a must. Due to the fact that they pay through taxes, or other kind of payments, they want the best Health Care system at the cheapest price. By contrast, in the USA around 50% of citizens think that it is not the Federal Government's responsibility to make sure all Americans have Health Care coverage (Newport, 2010). The EU is going towards free access to the services throughout the EU, with similar standards in terms of doctor and nurse skills, drugs, medical devices, hospital infections and safety, even if there are no common rules concerning the kind of organisation to implement; this latter is a matter left to each country. During the past decades each EU country has spent more and more money in order to improve Public Health Care services to the extent that nowadays the expenditure is almost unaffordable. The last economic crunch has dramatically affected EU countries and they have started to reduce and rationalise Health Care expenditure.

In such a scenario why does this research propose differences from the manufacturing sector? The medical doctors interviewed and the respondents to the survey questionnaire agree that there are important differences in implementing Six Sigma in the two sectors. First of all, in the manufacturing sector savings drive Six Sigma projects. It is quite impossible to launch a Six Sigma project without filling in a cost justification chart measuring expected savings (Pyzdek, 2003). Public Health Care Departments sometimes are bound to carry out improvement projects without savings or might even add costs. It has been found through grounded theory that the core category is 'the product is the patient'. The concept of 'customer satisfaction' itself is completely different. In the manufacturing sector Six Sigma leads to the reduction of DPMO, as discussed in the third chapter, mainly because customers' satisfaction means more customers and consequently more turnover. In many countries in which the National Health System is based on Lord Beveridge principles, Public Health Care organisations are a sort of monopoly. Customers can choose private and more expensive organisations only if they can afford it. Therefore customer satisfaction as a leverage to increase the number of customers and the turnover in Public Health Care is almost not applicable. Table 8.2 shows some Six Sigma projects carried out with the purpose of improving patient satisfaction without savings or even increasing costs.

Ultimately, profits and savings are not the only reasons for applying Six Sigma in Public Health Care. Their results have to meet the regulations, local political issues and several other stakeholders involved such as patients' rights associations and civic NGO representatives. In the manufacturing sector, simplifying the concept, the market drives Six Sigma projects.

Table 8.2: Example of Six Sigma projects with negative economic–financial impacts

Six Sigma project	Objective – Characteristics CTQ	Economic–financial impacts

Waiting time reduction for 'Orphan Drugs' administration	Reducing the time for the patient who is waiting for the supply from pharmaceutical industry. The waiting time (CTQ) can be reduced by at least 1 week	Increase by 18% of the total cost of drug management. This is due to a new contract with two pharmaceutical companies
Increase of patient satisfaction during radiotherapy treatment	Improvement of the hospitality in the waiting room measured by a periodical survey (CTQ)	Estimated expenditure of 50,000 euros for refurbishments and new services for the patients

8.3.3 Climate and rules in Health Care can affect Six Sigma results

This is probably the most interesting point of difference from the manufacturing sector. Current Health Care improvement projects, led by the means of Six Sigma tools, Lean Thinking, TQM or any other management system for excellence, surely need a multidisciplinary approach (see Chapter three). It is well known how concepts such as teamwork, changing behaviour, team organisation and many others can affect results in any sector including Health Care (Tjosvold, 1991; Firth-Cozens, 1998; Firth-Cozens and Payne, 1999). However, as discussed in the previous chapter, European Public Health Care is quite different from manufacturing or the private service industry. In these latter the organisational and climate aspects can be improved more easily, even by changing rules and people.

The first obstacle is medical education and training. Both in Europe and America, doctors and nurses have followed an educational model derived from the nineteenth century (Chassin, 1998) in which doctors are trained as clinical decision makers rather than as team leaders or team members. In the past decades Europe has changed its approach and universities and medical schools have introduced Masters and courses dedicated to the managerial aspects but basically a medical doctor is supposed to measure himself or herself on clinical results. In this way most doctors have little vocation for management (Atun, 2003) because they believe this adds unnecessary work to their clinical mission. Vlastarakos and Nikolopoulus (2007) assessed European Public Health practitioners on the interdisciplinary model of hospital administration concluding that most health practitioners consider an interdisciplinary model ineffective. Of the interviewed doctors 78% believed that there are problems and even conflicts with managers. Thus, a large part of European Public Hospital doctors still consider their duties in conflict with managerial tasks. In the interviews held inside two Italian hospitals some nurses declared that the Head of Department and sometimes doctors would be natural team leaders in Six Sigma projects. However, it seems that many doctors do not want to accept that role; this surely does not help Six Sigma implementation.

To make the situation more complicated there is the strict contracts of European Public Administrations. In many countries such as Italy, France, Greece and Germany, both doctor and nurse contracts are discussed with trade unions and it is not so easy to change the assigned roles and job descriptions. In discussing conflicts it is fundamental to underline what in Health Care is considered the most important kind of conflict: the relationship between doctors and nurses. Many authors dealt with the subject (Stein *et al.*, 1990; Porter, 1991; Sweet and Norman, 1995; Svensson, 1996; Salvage, 2000; Skinner and Bramhall, 2003; Sclamber, 2008) even if there is no trace of literature concerning conflicts within European Public Health Care Six Sigma projects. Doctors and nurses historically have different and separated roles. Patients have perceived these differences since Public Health Care began; in fact patients think that nurses can manage simple conditions but have more specialisation and competence in particular areas (Halcomb, 2010). These areas during the past years have been expanding from simple operative conditions to more complex and managerial roles. For instance, in Italy at the beginning of 2000, nursing studies was transformed from a Diploma to a BSc, and several Masters in managerial subjects have been designed by Italian universities. Hence in the current Public Health Care situation nurses are raising their skills towards a more managerial role and at the same time doctors are still more focused on clinical aspects. If a hospital decides to manage a Six Sigma project, Heads of Departments and doctors are thought of first as natural leaders such as Master Black Belts or Black Belts, but afterwards the role so appointed can create difficulties in terms of leadership and even can be questioned by some nurses. This is what clearly emerged from the interviews and the focus group analysed in the fifth chapter.

Furthermore the rigid contracts for both doctors and nurses that are always discussed with the trade unionists in large part of the EU does not help to appoint the right staff for the right Six Sigma project. In countries such as Italy, if someone has a contract as, for instance, a laboratory technician, then it is difficult for that professional to commit himself/herself to other roles, and even more so because the organisation will pay him or her just for the laboratory job and not for other roles such as Black or Green Belt.

Lastly, in countries such as Italy, the previously investigated conflict between General Managers, Heads of Departments and doctors due to local political relations has also to be taken into account. All these factors can surely affect the results of a complex Six Sigma project in which relationships among the participants, team efforts, leadership, commitment and involvement are the most important 'ingredients'. Once more, in Italy the situation is made more complex by the fact that doctors and nurses advance their careers through public competitions in which often having to participate in managerial projects such as Six Sigma or Lean Thinking does not make any difference with the examination board.

Table 8.3 synthesises what are the most important elements of the organisational climate inside a European Public Health Care organisation that can affect Six Sigma project results.

Table 8.3: Six Sigma projects can be affected by climate and organisational roles

Element	**Influence**
Doctor and nurse education and training	Clinical facts rather than managerial aspects in the projects

Doctors focused on clinical processes	Doctors sometimes are less involved in Six Sigma projects because they are 'time consuming'
	Doctors appointed as team leader but sometimes not recognised like that
Doctors and nurses have a strict professional contract	Difficulties in raising awareness and involvement in Six Sigma projects
	Negotiation with trade unions for important roles
	Little or no awards for Six Sigma results
Nurses have been acquiring managerial skills	Conflicts for the leadership inside teams
Heads of Departments appointed by General Managers	Conflicts among General Managers, Heads of Departments and doctors especially in countries like Italy where politics can influence decision making

8.3.4 Other minor differences from the manufacturing sector

8.3.4.1 Risk management tools are slightly more important than other tools

Risk management is something of a very general implementation. Risk management can be applied in evaluating business risks, safety risks, environmental risks and product/service risks. Six Sigma inherits TQM tools concerning Risk management, in particular tools for improving product/service design and process development (Yang and El-Haik, 2009). Therefore in every sector Six Sigma teams deal with such tools in the early phases of product/service and process design. In the manufacturing sector Risk management is applied once engineers have issued the preliminary drawings and technical specifications, then on the prototype or pre-series before launching the real production. In this way QFD is used to better understand what the customers' needs are and how they should be implemented in the product and process (Kano *et al.,* 1984). FMEA evaluates potential risks inside the product/service or process, finding their potential causes and calculating a ranking of the risks (Stamatis, 2003). Other common tools employed in Risk management are cause and effect diagrams, designed experiments, simulations and probabilistic design (Mader, 2002).

The respondents to the questionnaire used in the sixth chapter underlined that there is not conceptually any difference between Health Care and other sectors. However, reviewing the results of the qualitative methods such as the interviews and the focus group, some minor details come to light. As previously discussed, triangulation between quantitative and qualitative methods can move the researcher from the general model to its details and vice versa. In this way it can be claimed that even if Risk management is applied in all the sectors, what makes the real difference is the 'intensity' of the use inside Six Sigma projects. As discussed in the previous chapter, the outcome of a caring process is something in which defects must be at zero level; consequently all the risks must be evaluated and managed whatever the situation is. During any Six Sigma project that can slightly affect patient health or the relative cures, teams are obliged to evaluate potential new introduced risks as well as the impact on the existing ones. This is similar only to manufacturing sectors such as nuclear, aerospace and pharmaceutical.

8.3.4.2 The use of the statistical tools

Many kinds of tools are used inside the DMAIC pattern and they are mainly inherited from TQM and Lean Thinking. Even if Lean derives culturally from Japan and in particular from the carmaker Toyota it has joined Six Sigma to form Lean Six Sigma; hence its tools such as 5S, SMED, TPM and many others are used inside the DMAIC pattern. As confirmed in the sixth chapter, the respondents to the questionnaire believe that both in the European Public Health Care and manufacturing sector all kind of tools can be used including statistical ones. However, after a deeper analysis of the results of the interviews with the two Italian doctors and a review of the literature about clinical background, it seems that doctors and nurses are not interested in statistical subjects. Respondents claim again that statistics is important in whatever industry especially for problem solving but how does this deal with the weaker statistical background of doctors and nurses? It is likely that doctors and nurses during their Black or Green Belt qualifications are not so eager to study and apply statistics, in particular advanced statistical tools such as ANOVA, DOE and Multiple Regressions. Is Health Care less accustomed to advanced statistical tools within Six Sigma projects? Is the reason because they often prefer Lean Thinking? The two interviewed Italian doctors confirmed this but it should be confirmed by a larger sample of Health Care professionals.

8.3.4.3 Managing the organisation as a whole

The respondents to the questionnaire confirmed that in both sectors it is important to manage Six Sigma in all the departments and processes. Six Sigma cannot be applied in a single office or just as a trial; as discussed in the third and seventh chapters, it needs a link to the strategies and a 'visionary' and strong senior management commitment because the entire organisation must be driven towards the goals. Hence it becomes important to analyse the processes and their links as well as involve the supply chain. This 'holistic' vision of Six Sigma becomes fundamental in complex Health Care organisations such as public hospitals in which the 'product'/patient is managed by several departments. For instance, a patient can arrive at the emergency department, can need an urgent radiology examination, a laboratory examination and to be finally moved to outpatient surgery. All these departments are little companies with their own managers and processes and in the end it could be dreadful if these little companies did not work 'in unison'. A surgeon cannot wait a long time for a laboratory report or worse receive a wrong report; faultiness is not an option. Often in the manufacturing sector medium and large enterprises implement Six Sigma and have found involving their small suppliers difficult. Antony *et al.* (2005) demonstrated how small- and medium-sized enterprises have unsuccessfully applied Six Sigma. In this case the company that is applying Six Sigma can anyway better inspect the incoming products of the suppliers with extra costs such as inspectors and inventories. It is not the best solution but at least the eventual lack of quality due to the supplier is quickly stopped. In Health Care each department has many internal small suppliers and it is difficult to check all the incoming products and services received from them. Can a surgeon waste time in order to check a laboratory report? It is impossible, especially when there is a very urgent case. If in the manufacturing sector Six Sigma can be applied without sometimes involving suppliers and internal departments, then in Health care this is very difficult because the consequences to the patient could be a disaster.

8.4 Conclusions

In this chapter the differences that have emerged in the previous chapters have been analysed further and discussed. These differences represent the important principles of the European Public Health Care sector shaped in the seventh chapter. Ten epistemological assumptions were found in the seventh chapter and compared to the manufacturing ones. However, the research cannot be considered completed; indeed the differences found open an interesting and wider debate on European Public Health Care. Not all the details are once and for all defined and they need more investigation. In addition, the discussion has brought to light new, and sometimes unexpected, details that are worth further research. In the next and last chapter the limits of this research will be presented as well as a possible future agenda for new research.

Chapter 9 – Conclusions and agenda for future research

9.1 Introduction

In the seventh chapter the European Public Model was defined and compared with the manufacturing one. This has been a long journey that started from the results of a deep literature review, two interviews with Italian doctors, a focus group and observations within Italian Hospitals. The outcomes of this first qualitative inquiry have been analysed using grounded theory and the resulting categories linked to each other. A core category has been identified and labelled as 'the product is a patient'. The seventh chapter also deals with the human aspects of this issue.

Ontologically assuming that excellence in Health Care should be the 'product patient' and its complete satisfaction at any cost, differences in the way of implementing Six Sigma have been found. By comparison with the manufacturing model, ten epistemological assumptions were found and discussed. The differences that emerged from grounded theory have been transformed into hypotheses and tested by means of a Chi-square test. In the end three out of ten hypotheses are considered the real and general differences from the manufacturing sector. Triangulating from qualitative to quantitative to qualitative once more and reviewing the details of the interviews, the focus group and the participant observation, more particular details have highlighted the differences in the models. Surely these details are 'feeble signals' that help the research to better shape the model and open new debates on the subject.

9.2 Conclusions of the research

The research has reached its main goal of finding a Six Sigma model for European Public Health Care. The theoretical model is based on ten principles linked together starting from the core category 'the product is the patient' and this is, in a philosophical way, the ontological foundation of the model. Being excellent in European Public Health Care means to bear the patient and his/her satisfaction always in mind, sometimes forgetting what profit and income are. Table 9.1 summarises the ten principles of Figure 7.1 found and discussed in the seventh chapter on which the model is based. The table also tries to link the ten principles of the model with the way of implementing it based on the ten epistemological assumptions shown in Table 8.1. The third column sums up the kinds of differences, major or minor, as discussed in the previous chapter.

Table 9.1: The ten principles of the model and the way of implementing it

Category	Way of implementing it (Epistemological assumptions)	Differences from the manufacturing sector
Strategic objectives linked to local authority	Requires top management high commitment and involvement. Political influences	Relevant differences especially in a country such as Italy in which Regional politicians affect Public Health Care
Economic results balanced with other factors	Improves the quality performance, particularly COPQ, cost reduction is sometimes inevitably balanced with patient satisfaction	High difference from the manufacturing sector. Patient satisfaction and treatments first of all
Zero defects and Risk management on the caring processes are expected	Reduces variation within the processes. Zero defects and reduced risk for health of patient as a result Requiring focus and capture of the voice of the customer. Definition	Risk management tools are more expected and more important than other ones

	of critical characteristic for patient	
Six Sigma should be applied in the whole hospital	Focuses on improving processes of the whole organisation through DMAIC approach. Risk of application in few departments because of obstacles inside senior management	It is important for both sectors but in Public Health Care it is more difficult to manage Six Sigma in a single or few departments
Statistical tools are better for problem solving inside activities	Uses of all kind of tools derived from quality and other management systems. Lean tools important for mapping patient flow and reducing lead times	No differences at all. Statistical tools are important when a Six Sigma project is based on a root-cause analysis
Statistical tools are suitable for Health Care as well	Requires also skills based on statistics and data, even if statistics is not the background of doctors and nurses	No differences. Statistical tools are important for both sectors. Doctors and nurses are just a little less accustomed to using statistical tools
Lean mapping tools (VSM) are more suitable for the whole flow	Uses of all kind of tools derived from quality and other management systems. Lean tools important for mapping patient flow and reducing lead times	There are no differences. Lean mapping tools, in particular VSM, are important to see the patients' whole flows
DMAIC is always used as a pattern	Involvement of employees. Team oriented and use of certified Black and	There are no differences. DMAIC pattern is the Six Sigma DNA

	Green Belts	
No need of Black and Green Belts for short and Lean-based projects	Focuses on improving processes of the whole organisation through DMAIC approach. Risk of application in few departments because of obstacles inside senior management	There are no differences. If the project is quick or based only on Lean tools it does not need any Black or Green Belts
Climate and rules can affect results	Short- and medium-term improvement project but long-term cultural change. Politics, trade unions and strict roles and responsibilities do not help to reach this radical change Self-empowerment and responsibility. Failure risks due to strict roles and responsibilities	Relevant differences from manufacturing. Doctor and nurse contracts are stricter in Public Health Care. There are more conflicts within the teams

In the end the European Public Health Care model shows two major kinds of differences:

- A strong emphasis on patient satisfaction that leads sometimes to Six Sigma projects and general improvements being conducted without any profit or income.
- The organisational climate and the strict rules can lead to the failure of a Six Sigma project more frequently than in the manufacturing sector.

The reasons are discussed in detail in the seventh and eighth chapters.

There is another major difference from the manufacturing sector but it seems just an Italian issue. Italy has the strongest political influence on strategic objectives for Public Health Care. As discussed in the eighth chapter, Regional politicians can appoint General Managers and ask for a particular objective to be achieved. This means that the results of a Six Sigma project can be linked to the will of politicians.

Another peculiarity of the European Public Health Care model concerns the mandatory use of Risk management tools inside Six Sigma projects. This is due to the special care that is needed with every patient treatment or diagnosis. As discussed in the eighth chapter this is something similar to the nuclear, aerospace or pharmaceutical industry.

Two last minor differences are the doctors and nurses' weak use of statistical tools even if they are considered fundamental, and the difficulties to implement and manage Six Sigma in only a few departments. This latter problem can also be found in the manufacturing sector but it seems that in this sector it can be figured out by, for example, means of more incoming inspections.

It is important to notice that these three last minor differences were derived from the qualitative results of the interviews, the focus group and the observation and therefore they depend on the particular Italian context and cannot be generalised. In fact, concerning the weak use of statistical tools, some numeric clues have been founded in the cross tabulation tables in the sixth chapter.

But how can the results of this research can be compared with the results of the literature review? Chapter three has brought to light that no model for European Public Health Care sector has been depicted yet. Some authors even consider the manufacturing model suitable for the health care industry as well. Nonetheless other authors (Moullin, 2008; Moullin and Soady, 2008), underlined that the needs and requirements of patients in health care differ from patient to patient whereas manufacturing product requirements have much more repeatability. This is an important issue confirmed in some way also by the results of this research. Indeed, compared to the manufacturing sector it has emerged that doctors and nurses are a bit reluctant to use statistical tools.

Maybe this is related to the fact that, as Moullin (2008) suggested, needs and requirements differ from patient to patient, consequently it is sometimes difficult to gather consistent data. Many statistical tools require lot of data gathered from similar processes, however in the health care organisations patients have often very different care processes, even for the same disease.

The intense use of Risk Management can also be related to Moullin's discussion. Risk Management is based on personalized analyses (De Rosier *et al.,* 2002) that can differ from patient to patient and from process care to process care. Once more this is something strictly related to the health care industry.

These issues bring original contributions to knowledge for both academics and practitioners. First of all this research claims that Six Sigma is not always a model devoted to the reduction of costs as many of the reviewed authors affirm. In the European Public sector cost reduction can sometimes be in the background. Academics and practitioners have also to take in serious consideration that Six Sigma could not be enthusiastically accepted by European Health Care people. Some authors (McAuley *et al.,* 2007*)* introduced criticisms to New Wave management theories and Six Sigma, as previously discussed, can surely belong to such theories. In particular this research shows how organisational climate and strict rules can lead to the failure of a Six Sigma project more frequently than in the manufacturing sector. As a matter of fact doctors and nurses do not have an engineering and mechanistic attitude to solve problems using for instance advanced statistical tools. It is very interesting that research process changed the researcher's point of view. Indeed at the beginning, the researcher started his path with a deductive quantitative model in mind. This surely belongs to the inquiry traditional methods of Engineering. During the process, the researcher has widened his horizons studying Social Science methods and most of all discussing inquiry methods with his supervisor. This has led the researcher, first of all, to introduce new qualitative methods such as focus group and participant observation. Secondly to deal with the so-called triangulation. The new horizons that the researcher discovered have also led him towards a different point of view concerning the European Public Health Care sector. McAuley *et al.* (2007) introduced criticisms to New Wave management theories and models such as Six Sigma. As discussed in the third chapter, formal and distant control can lead to failures. Six Sigma applied in the manufacturing sector is derived from a typical engineering conception of organisation. In this way, the researcher at the beginning believed that Six Sigma could be applied with a similar approach to the public health care sector without any kind of failures. A different model but in any case based on technicality and precise rules. However, the researcher, having enhanced his knowledge, has found out interesting aspects linked to organisational climate that can not be discovered from an engineering point of view. Conflicts, hierarchical relationships, political aspects, motivation, as well as team efforts do not belong to the Six Sigma DMAIC pattern. Furthermore in the European Public Health Care sector these aspects are more important than in the manufacturing one. They surely bring up for discussion the perfect and formal engineering clockwork. If the researcher had followed just a quantitative and deductive approach this aspect would have never come out.

Lastly, the results of this research bring important suggestions for practitioners. In applying Six Sigma inside the European Public Health Care industry it is fundamental to manage the organisation as a whole. Tools for mapping the processes must be used as well as risk analysis for reducing all kind of mistake. 'The patient is the product' is the core category considered part of the ontological assumption of the model.

Limitations of Six Sigma in the health care can be interesting for practitioners as well. The third chapter has highlighted how not every kind of improvement projects can be carried out using Six Sigma. This is also confirmed by the results of the observations in the qualitative stage. Indeed, it has been founded that patients can express personal views about their own conditions, which should be useful in planning improvements in care. In this particular case statistics and even the Six Sigma DMAIC pattern cannot be useful. For instance, if a public hospital wants to improve patient satisfaction concerning particular and very personal treatments, many Six Sigma tools are useless. Patient satisfaction can sometimes significantly vary depending on unmeasurable factors such as courtesy, hospitality and empathy. On the contrary, Six Sigma and its tools can be fundamental, in the health care, when it is important to analyse correlations among measurable factors such as patient satisfaction, errors, costs, times, physical states, infections, and many others. In this case data can be more easily gathered avoiding psychological and personal influence aspects.

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9.3 Strength points and limitations of the research

This research has several strength points discussed in the previous chapters. First of all the originality; very few European health care organisations have applied Six Sigma and for the first time a research has tried to understand the differences from manufacturing industries. Beyond, for the first time, Six Sigma has been located in a philosophical way for both health care and manufacturing sectors, discussing about the ontological and epistemological assumptions of the model.

The research methodology is based on a triangulation between qualitative and quantitative inquiries in order to make it more generalisable. The results of the grounded theory have been transformed into hypotheses, even if some authors claim that grounded theory results are applicable in the world at large (Yin, 1994), thence they do not need any validation.

Limitations of the research are mainly due to the fact that so far very few European public health care organisations have applied Six Sigma in the organisation as a whole. It has been very difficult to find public health care organisations in which gathering data and information about Six Sigma. As discussed in the fourth chapter the research methodology could seem limited in the qualitative stage because of a small sample of two hospitals for the analysis. Anyway the large quantity of information and data gathered through the interviews, the focus group and the observation have generated issue concepts and theoretical categories subsequently validated as hypotheses. The two founded hospitals are in Italy and this could have affected the final results. As already discussed, Italian health care system shows different features from the other European countries. In any case, according to chapter 1 common elements can be found. First, as discussed in Subsection 1.1.1, European public health care organisations are linked mainly to public funds. Second, European health care services share many objectives such as patient satisfaction and the reduction of waiting lists, infections and mortalities. Another interesting common element is related to the size and the organisation of hospitals. Lastly the contracts of employment of doctors and nurses are also similar across Europe, as well as their university backgrounds and trade union schemes.

These common elements justify the use of the Italian health care system as a foundation for the research.

Furthermore it has been founded that the European Public Health Care differs from manufacturing in three expected differences. The influence of the local authority on the Six Sigma results and the balancing of the economic results with other results such as patient satisfaction as well as the influence of organisational climate can be suggested by 'common sense'. Indeed there is a wide literature on the subjects and the first two differences have been taken for granted and not tested in the quantitative stage. In any case the model shaped in figure 7.1 should be interpreted as a whole along with its ten differences from manufacturing. The model in figure 7.1 shows a 'story line' and the relationships among the theoretical principles that underpin Six Sigma for the European Public Health Care. This is the most important and original contribution to knowledge of this research.

9.4 Agenda for future research

This PhD research has shaped a new model for the European Public Health Care sector and highlighted some differences from the manufacturing sector as shown in Table 9.1. As discussed in the second and third chapter, traditional manufacturing Six Sigma is now well known and plenty of literature has been written since the 1990s and academics and practitioners have already defined numerous theoretical principles of the model. In this way the ten epistemological assumptions found in the third chapter represent a synthesis of that and give to the model a precise philosophical collocation.

The application of Six Sigma to European Public Health Care is more recent and naturally it has fewer case studies and literature to investigate. In the light of this, the results of this research could be analysed further and discussed especially by the academic community. Surely, the first and most important subject to investigate is the influence of the organisational climate on Six Sigma results. The results of the qualitative stage have been validated and generalised through Chi-square tests and it seems that the respondents to the questionnaire consider that Health Care is a sector that differs from manufacturing. The kind of contract for doctors and nurses, their background, the rules, conflicts between the General Manager and the Head of Departments, union power and other aspects discussed in the seventh and eighth chapters can affect or even shelve a Six Sigma project. Academics and practitioners, using qualitative inquiries, could analyse European Public Health Care cases in order to better understand what the reasons are. In addition it could be very interesting to compare the European Public Health Care system with US Public Health Care or Asian Public Health Care in an attempt to understand what the differences are in terms of organisational climate inside Six Sigma teams.

Another quite indisputable matter is the trade-off between cost reduction and quality of the medical care and treatment. Academics could investigate for example by the means of case studies what the 'triggers' are and the boundaries of these particular situations. Six Sigma projects in which savings have been taken into a minimum or no account should be analysed and discussed.

Furthermore the results of the research show some differences in the kind of tools that should be using during the DMAIC pattern. These results emerged from a second review of the qualitative results and they are not tested in a quantitative way. It seems that risk analysis and risk management tools are more important than other tools. By analysing Health Care studies academics and practitioners could better investigate: what these tools are, when during the DMAIC pattern the team is supposed to use them and what kind of results they can reach. Looking at the results of the interviews it seems for instance that FMEA is one of the most used. It is also important to investigate the effects of applying Six Sigma in one or few departments instead of the organisation as a whole. This can happen in manufacturing as well but it seems that the effects can affect Six Sigma results more heavily. This could be linked to the fact that Health Care services are sometimes more difficult to check than physical products from the shop floor or from the suppliers.

It could be interesting to analyse when European Public Health Care managers prefer to use Lean Thinking tools instead of Six Sigma tools. It surely depends on the scope of the project; for instance if an improvement team wants to find out what the root causes of a phenomenon are they can use a Six Sigma–DMAIC pattern. Otherwise if the project is a matter of time reduction, like patient waiting lists or the patient path within departments, Lean tools could be more useful. However, it seems that cultural aspects like the not so oriented towards statistics background of doctors and nurses can affect the choice.

The long journey has also brought interesting 'food for thought' regarding the use of Six sigma in health care. At the beginning it seemed that a model based on Six Sigma could be applied to the European Public Health Care sector in the same way it is applied in the manufacturing sector. However, after having reviewed literature concerning Six Sigma and Lean Thinking, and compared them in a philosophical way, some doubts emerged. In the manufacturing sector Six Sigma surely needs Lean Thinking, but it could be that in the European Public Health Care sector Lean is more important than Six Sigma and that Lean does not need to be supported by Six Sigma. Maybe a massive application of Lean inside caring processes along with the application of some of the Six Sigma tools would be enough to achieve patient satisfaction as well as zero defects and cost reduction. Besides, according to the results of the qualitative inquiry and cross tabulations in the appendix C, it seems that doctors and nurses are less accustomed to using advanced statistical tools. The latter could influence the choice of a Lean model instead of a Six Sigma one. More research in this direction should be done by academics and by practitioners.

Another interesting aspect that comes up from cross tabulations, even if not deeply analysed, is that the DMAIC is considered more important by doctors and nurses in the health care than in the manufacturing sector. More research in this direction should be done by academics and by practitioners.

Last but not least, a subject to investigate could be the influence of politics on Six Sigma strategies in Public Health Care organisations. In countries like Italy this is quite indisputable but a comparison among the different European Health Care systems could be carried out in order to understand if this is just an Italian phenomenon.

APPENDIX A

Draft aide memoire (interviewer guide)

1. Good morning doctor, you are interviewed as an expert of Six Sigma and Total Quality Management. How long have you been dealing with Total Quality Management in the Health Care sector? (try to understand if the person is really an expert of Six Sigma as many believe that he is)
2. Besides the project that we will discuss soon, have you managed other similar projects? (I am always trying to understand his skills on the matter)
3. How long has the project Six Sigma lasted and what role do you have in the project (try to understand if he has a deep knowledge of the project)
4. Who has sponsored the project? (he enters the technical part of the interview)
5. Was the project linked to strategic objectives of the business plan?
6. And what kind of objectives? (Try to understand who decides the objectives)
7. How did you appoint the members of the Six Sigma team? (using ethnographic way I try to understand if the team was really a team with TQM skills or something more similar to friendship) Note: try to avoid in this point collecting the names and last names of the people because the interviewer does not have their consent (ethical considerations on privacy)
8. Did you train your team in a particular way (e.g. Black and Green Belt certification)
9. How did you choose the team leader?
10. Did you structure the classic DMAIC path in other ways?
11. What kind of tools did you use during the path? (this is the core of the evaluation of the hypothesis)
12. What kind of statistical tools did you use?
13. Do you believe that advanced statistical tools can affect the results of a Six Sigma project?
14. Do you also use Lean tools and in what circumstances?
15. What about the skills of the participants?
16. And what about the awareness and behaviour of the team participants? (very open question; take care on the discourses of the medical doctor on the particular organisation in Health Care, how to involve the participants,

their cultural background, the involvement of the unions, if the participants claimed for an increase in salary etc.)

17. Did you manage internal conflicts among the participants, why and how?
18. What about the 'semiotic' inside the team? Was it the same used in the manufacturing field?
19. Could this kind of semiotic change the meaning of classic Six Sigma vocabulary?
20. Did the team achieve the desired results? Partially, totally?
21. Do you believe that only economic results are important in Health Care?
22. What other kind of results are important?

APPENDIX B

Focus group questionnaire

<table>
<tr><td>#:</td><td>Date:</td><td colspan="4">Team Leader:</td></tr>
<tr><td colspan="6">Focus:</td></tr>
<tr><td colspan="6">Participants:</td></tr>
<tr><td colspan="2">1) Have the participants already known Six Sigma?</td><td>Never before</td><td>Just a little</td><td>Yes</td><td>Yes, very well</td></tr>
<tr><td colspan="2">2) Do the participants know quality and Lean tools for improvement?</td><td>Never before</td><td>Just a little</td><td>Yes</td><td>Yes, very well</td></tr>
<tr><td colspan="2">3) The economic results are the most important</td><td>Agree</td><td colspan="2">Neither agree nor disagree</td><td>Disagree</td></tr>
<tr><td colspan="2">4) Do the participants know advanced statistical tools?</td><td>Never before</td><td>Just a little</td><td>Yes</td><td>Yes, very well</td></tr>
<tr><td colspan="2">5) Do the participants use tools taken from Lean Thinking?</td><td>Never before</td><td>Just a little</td><td>Yes</td><td>Yes, very well</td></tr>
<tr><td colspan="6">Debate with the participants:
- rules and roles inside the projects;
- organisational aspects;
- leadership and conflicts.</td></tr>
</table>

APPENDIX C

Cross tabulations by clusters, questions and answers

1

	Question 3 – Answers for the health care question (association between the sector and the zero defects and risk management tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	11	25	38	35	80	*189*
European doctors and nurses	15	7	25	65	119	*231*
Academics	14	42	9	55	32	*152*
Total	*40*	*74*	*72*	*155*	*231*	*572*

	Question 3 – Answers for the manufacturing question (association between the sector and the zero defects and risk management tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	11	12	30	51	85	*189*
European doctors and nurses	15	6	23	55	132	*231*
Academics	14	26	19	63	30	*152*
Total	*40*	*44*	*72*	*169*	*247*	*572*

2

	Question 4 – Answers for the health care question (association between the sector and the Six Sigma application in the whole organisation)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	11	41	30	58	49	*189*
European doctors and nurses	15	18	23	45	130	*231*
Academics	14	16	18	52	52	*152*
Total	*40*	*75*	*71*	*155*	*231*	*572*

	Question 4 – Answers for the manufacturing question (association between the sector and the Six Sigma application in the whole organisation)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	11	37	30	59	52	*189*
European doctors and nurses	15	18	23	48	127	*231*
Academics	14	16	18	52	52	*152*
Total	*40*	*71*	*71*	*159*	*231*	*572*

3

	Question 5 – Answers for the health care question (association between the sector and the use of statistical tools for problem solving)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	7	11	14	50	107	*189*
European doctors and nurses	20	36	30	62	83	*231*
Academics	14	26	29	43	40	*152*
Total	*41*	*73*	*73*	*155*	*230*	*572*

	Question 5 – Answers for the manufacturing question (association between the sector and the use of statistical tools for problem solving)					
Likert scale						*Total*
European consultants	7	11	14	50	107	*189*
European doctors and nurses	20	38	30	62	81	*231*
Academics	12	26	29	42	43	*152*
Total	*39*	*75*	*73*	*154*	*231*	*572*

4

	Question 6 – Answers for the health care question (association between the sector and the suitability of using statistical tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	0	1	10	52	126	*189*
European doctors and nurses	40	73	56	52	10	*231*
Academics	0	0	6	53	93	*152*
Total	*40*	*74*	*72*	*157*	*229*	*572*

	Question 6 – Answers for the manufacturing question (association between the sector and the suitability of using statistical tools)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	2	2	13	56	116	*189*
European doctors and nurses	39	70	50	40	32	*231*
Academics	0	0	10	60	82	*152*
Total	*41*	*72*	*73*	*156*	*230*	*572*

5

	Question 7 – Answers for the health care question (association between the sector and the use of Lean mapping tools for the whole flow)					
Likert scale	*1*	*2*	*3*	*4*	*5*	*Total*
European consultants	15	16	16	54	88	*189*
European doctors and nurses	13	32	27	57	102	*231*
Academics	12	26	29	45	40	*152*
Total	*40*	*74*	*72*	*156*	*230*	*572*

	Question 7 – Answers for the manufacturing question (association between the sector and the use of Lean mapping tools for the whole flow)					
Likert scale						*Total*
European consultants	15	16	16	54	88	*189*
European doctors and nurses	13	33	30	57	98	*231*
Academics	11	26	26	45	44	*152*
Total	*39*	*75*	*72*	*156*	*230*	*572*

6

	Question 8 – Answers for the health care question (association between the sector and the use of DMAIC as a pattern)					
Likert scale	1	2	3	4	5	Total
European consultants	19	16	17	58	79	189
European doctors and nurses	10	43	40	67	71	231
Academics	11	15	16	30	80	152
Total	*40*	*74*	*73*	*155*	*230*	*572*

	Question 8 – Answers for the manufacturing question (association between the sector and the use of DMAIC as a pattern)					
Likert scale						Total
European consultants	9	19	16	65	80	189
European doctors and nurses	20	40	40	60	71	231
Academics	11	15	16	30	80	152
Total	*40*	*74*	*72*	*155*	*231*	*572*

7

	Question 9 – Answers for the health care question (association between the sector and the need of BB and GB when the Six Sigma project is short or entirely dedicated to Lean)					
Likert scale	1	2	3	4	5	Total
European consultants	9	19	32	70	59	189
European doctors and nurses	15	20	27	55	114	231
Academics	14	39	10	30	59	152
Total	*38*	*78*	*69*	*155*	*232*	*572*

	Question 9 – Answers for the manufacturing question (association between the sector and the need of BB and GB when the Six Sigma project is short or entirely dedicated to Lean)					
Likert scale						Total
European consultants	9	19	31	70	60	189
European doctors and nurses	15	20	27	55	114	231
Academics	14	39	10	30	59	152
Total	*38*	*78*	*68*	*155*	*233*	*572*

8

Question 10 – Answers for the health care question (association between the sector and the possibility that climate and rules can affect the results)

	Likert scale	*1*	*2*	*3*	*Total*
European consultants		24	25	140	*189*
European doctors and nurses		29	39	163	*231*
Academics		10	3	139	*152*
Total		*63*	*67*	*442*	*572*

Question 10 – Answers for the health care question (association between the sector and the possibility that climate and rules can affect the results)

	Likert scale	*1*	*2*	*3*	*Total*
European consultants		140	27	22	*189*
European doctors and nurses		170	39	22	*231*
Academics		99	33	20	*152*
Total		*409*	*99*	*64*	*572*

9

European consultants	*Respondents by questions to the 'Strongly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	11	11	7	0	15	19	9	#
Manufacturing counting	11	11	7	2	15	9	9	#
Percentage change	0	0	0	n.a.	0	52.6	0	#

European doctors and nurses	*Respondents by questions to the 'Strongly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	15	15	20	40	13	10	15	#
Manufacturing counting	15	15	20	39	13	20	15	#
Percentage change	0	0	0	2.5	0	100.0	0	#

Academics	*Respondents by questions to the 'Strongly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	14	14	14	0	12	11	14	#
Manufacturing counting	14	14	12	0	11	11	14	#
Percentage change	0	0	14.3	n.a.	8.3	0	0	#

10

European consultants	*Respondents by questions to the 'Slightly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	25	41	11	1	16	16	19	#
Manufacturing counting	12	37	11	2	16	19	19	#
Percentage change	52.0	9.8	0	100.0	0	18.7	0	#

European doctors and nurses	*Respondents by questions to the ' Slightly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	7	18	36	73	32	43	20	#
Manufacturing counting	6	18	38	70	33	40	20	#
Percentage change	14.3	0	5.5	4.1	3.1	7.0	0	#

Academics	*Respondents by questions to the ' Slightly disagree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	42	16	26	0	26	15	39	#
Manufacturing counting	26	16	26	0	26	15	39	#
Percentage change	38.1	0	0	n.a.	0	0	0	#

11

European consultants	*Respondents by questions to the 'Neither disagree nor agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	38	30	14	10	16	17	32	#
Manufacturing counting	30	30	14	13	16	16	31	#
Percentage change	21.1	0	0	30.0	0	5.9	3.1	#

European doctors and nurses	*Respondents by questions to the 'Neither disagree nor agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	25	23	30	56	27	40	27	#
Manufacturing counting	23	23	30	50	30	40	27	#
Percentage change	8.0	0	0	10.7	11.1	0	0	#

Academics	*Respondents by questions to the 'Neither disagree nor agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	9	18	29	6	29	16	10	#
Manufacturing counting	19	18	29	10	26	16	10	#
Percentage change	111.1	0	0	66.7	10.3	0	0	#

12

European consultants	*Respondents by questions to the 'Slightly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	35	58	50	52	54	58	70	#
Manufacturing counting	51	59	50	56	54	65	70	#
Percentage change	45.7	1.7	0	7.7	0	12.1	0	#

European doctors and nurses	*Respondents by questions to the 'Slightly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	65	45	62	52	57	67	55	#
Manufacturing counting	55	48	62	40	57	60	55	#
Percentage change	15.4	6.7	0	23.1	0	10.4	0	#

Academics	*Respondents by questions to the 'Slightly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	55	52	43	53	45	30	30	#
Manufacturing counting	63	52	42	60	45	30	30	#
Percentage change	14.5	0	2.3	13.2	0	0	0	#

13

European consultants	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	80	49	107	126	88	79	59	140
Manufacturing counting	85	52	107	116	88	80	60	22
Percentage change	6.2	6.1	0	7.9	0	1.3	1.7	#

European doctors and nurses	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	119	130	83	10	102	71	114	163
Manufacturing counting	132	127	81	32	98	71	114	22
Percentage change	10.9	2.3	2.4	220.0	3.9	0	0	#

Academics	*Respondents by questions to the 'Strongly agree' answer*							
	3	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Health care counting	32	52	40	93	40	80	59	139
Manufacturing counting	30	52	43	82	44	80	59	20
Percentage change	6.2	0	7.5	11.8	10.0	0	0	#

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List of Tables

List of Figures