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Technology Governance in Radiology: The example of Magnetic Resonance Imaging

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Technology Governance in Radiology The example of Magnetic Resonance Imaging [1]

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Abstract

This report aims to be the gathering of the main ideas that culminated in the presentation at the 1st Winter School of the PhD Programme on Technology Assessment (FCT-UNL) in December 2010. It is a guideline for future work development regarding Technology Assessment in Radiology, particularly having Magnetic Resonance Imaging, as an example. Therefore, as a background, it is necessary to understand what is "Technology Assessment", how it developed and what it Europe's interest in this area.

Doing a transposition of this subject to health area, it is also important to understand the particularities of Health Technology Assessment. Portugal framework on this subject will also be addressed. As so, the Portuguese National Health System is characterized and

[1] Based on the report for the unit "Project III" of the PhD programme on Technology Assessment in 2011. The unit was supervised by Prof. António B. Moniz (FCT-UNL).

the decision-making stakeholders identified, has well as the competences for the decision-making process in general.

More generally, the different stakeholders perception involved in decision making, the mapping skills on technology assessment and decision making, the identification of indicators present in this decision making in Radiology, particularly in Magnetic Resonance area, are subjects to be addressed. To accomplish this, a research methodology was outlined, so that six research questions could be answered and five hypotheses could be accepted or refuted, in the future. With this research methodology, the Portuguese state of the art Magnetic Resonance equipment existence will be studied, using a survey as a resource.

In the future, a mapping stakeholder technique will be used to identify the decision making key stakeholders and a survey will be applied to map theirs skills and competences in the process, where a pre-test was already applied.

Contents

Acronyms

HTA - Health Technology Assessment
MRI - Magnetic Resonance Imaging
NHS - National Health System
OTA - Office of Technology Assessment
TA - Technology Assessment
TG - Technology Governance
T - Tesla
WHO - World Health Organization

1. Introduction

We are facing an era, where pressures on health costs are extremely high, and the reforms in health system are almost constant. But over time, one factor remains unchanged: technology continues to be the support of health care improvement. Radiology is with no doubt, a clear example of technology application in order to obtain the medical examination of a patient. Radiology is also certainly a clear example of the application of technology to obtain exams of high importance in the diagnosis and the medical decision process, and treatment of numerous pathologies.

However, within this variety of existing technologies related with Radiology, one stands out ... Magnetic Resonance Imaging (MRI) differs from other imaging techniques, since it allows to obtain axial, coronal and sagittal images. It has also a high sensitivity to fluids movements, including blood and cerebrospinal fluid. This can be critical for an accurate medical examination. And MRI does not use x-rays radiation to obtain the images, since the images of tissues are based on their own physical and biochemical properties and there is some easiness in observing tissue surrounded by bone structures (cf. Tavares 1999).

Predicting the future of MRI exams is a speculative exercise, however it is easy to predict that this equipment will have a very exciting future with many benefits for users (patients). The accuracy can be improved to a much higher range, safety for the radiology technicians can be much improved, equipment maintenance can be easier and the usage costs can be better controlled.

But all of these only make sense, if it is considered in a Technology Governance (TG) environment, seen as a set of policies undertaken by the public and private sector and society actors in a given space in time to develop a knowledge base, social cohesion and competitiveness at the sometime[2].

A participatory methodology is considered in TG so that the opinion of the different actors can be taken into account. The identification of these actors (or decision-makers) is for that, extremely important and needed. These actors (citizens included) must be engaged and treated equally and given the some opportunity of participation. All actors must be responsible and participate with most transparency. Regarding the health sector, citizens (seen as potential patients) must be better informed and knowledge based, so that they can be more participative in their own health management and there for, more responsible. This is the proposal of the Technical Group for the Hospital Reform in the paper “Final Report - Citizens in the centre of the system. Professionals in the centre of change”.[3] One of the fundamental pillars of strengthening the role of users in health care relates to the ability of this influence decisions about health care, ie, the ability of users to access information, that it be clear and transparent, and that it will allow conscious and informed options and for that more demanding and driving quality and efficiency of services provided. Thus, the availability of information strongly conditions the user involvement in decision making. (Grupo Técnico para a Reforma Hospitalar 2011)

[2] See Tallinn University of Technology - Technology Governance website at http://hum.ttu.ee/tg/

[3] See: http://www.portaldasaude.pt/NR/rdonlyres/84FCFCE2-3C84-4ABE-8E5F-AD4DDB0B46F4/0/RelatorioGTRH_Nov2011.pdf

Another recommendation is also made by this Technical Group, has the role of the citizen, as the focal point of the health system should be strengthened to ensure that the entities that comprise the health system act in function of the citizen, by adjusting their behaviour to the actual needs of this, instead of the current situation of the health system, in which the citizen will have to adjust the provision of health care. With this new framework, the health system can be characterized by providing citizens accessibility to up-dated and consistent information, both regarding the health system and health information and by enabling citizens to be able to make informed and conscious decisions about their health, through the joint decision-making with health professionals.

If, ultimately, the decisions made in health care will affect the citizens (patients or not) it is expected that they have a say in the process. This is why, the new health politics tend to be more focused on patient and engage their involvement, perceptions and expectations. Like Facey *et al* say, "if we have moved to an era where patient's work in partnership with their health professional, rather than as the passive recipients of healthcare, it is reasonable that they participate in the Health Technology Assessment process" (Facey *et al*. 2010). According to Antunes (p. 136) the access to information is an unquestionable right, that goes along with the informed consent (Antunes 2001).

Citizens also must have a say in health technology assessment (HTA) area. HTAi (see 2.2.1 chapter) Interest Group on Patient /Citizens Involvement in Health Technology Assessment was created in 2005 and seeks to encourage and share best practice in engaging with patients and citizens throughout the HTA process and to promote methods of obtaining robust evidence for assessment of patient's perspectives.

2. Theoretical Framework

2.1. Technology Assessment

Starting with the definition of some important concepts, this chapter addresses the history and development of Technology Assessment (TA), first in the US and Europe. Different types of TA will also be mentioned, with special interest in Participatory TA. The aim of this chapter is to give a general main idea concerning TA contextualization.

2.1.1. What is Technology Assessment?

In 1996 US House of Representatives Subcommittee on Science, Research and Development published a report on the side-effects of technological innovation, which included a request for establishing an early warning reveal the positive and negative effects of technology probably in this report that the term 'technology assessment' was officially used for the first time (Tuininga 1988) under the chairman of Emilio Daddario. According to Arnstein (1977) and Coates (1971,1977), in early studies on technology assessment, it was defined as a form of policy research that examines short- and long- term consequences (for example, societal, economic, ethical, legal) of the application of technology (David Banta 2009).

According to the TAMI report (Europäische Akademie 2004) and to Bütschi, Decker and colleagues (Bütschi et al. 2004), TA is considered a scientific and communication process, which aims to contribute to the formation of public and their political opinion on social aspects of science and technology, and for that it is necessary to go further than mere economic studies.

2.1.2. The development in Technology Assessment

In the years following 1966 the methodology, practice and institutionalization of the objectives, basic concepts, working means and the prospects for formal recognition of TA have been put into concrete terms. Many TA studies were carried out and Congress's Office of Technology Assessment (OTA) was established by the Technology Assessment Act of 1972 (Tuininga 1988). The OTA was an office of the U.S. Congress from 1972 to 29 September, 1995[4]. OTA's purpose was to provide Congressional members and committees with objective and authoritative analysis of the complex scientific and technical issues of the late 20th century (David Banta 2009).

In 1980, Donald Lambro criticised OTA, calling it an "unnecessary agency" that duplicated government work done elsewhere. These critics were favoured by the Reagan administration. OTA was closed on September 29, 1995 (David Banta 2009). Regardless its closure, OTA served as an example and as a stimulate activity in TA for other American and also international institutions. The technology assessment movement soon spread to other countries, especially the highly developed industrialized countries, where it gained an increasing degree of influence in political debates on research and technology (Tuininga 1988).

2.2. Health Technology Assessment

The main objective of these sub-chapter is to make a thematic framework for HTA, using the definition of some key concepts. It is also intended to make the state of the art of HTA in Portugal, as well as addressing the evolution of this methodology around the world.

2.2.1. What is HTA?

One of the main challenges in health care is to improve the quality of health systems. For that it is necessary to establish mechanisms for transferring knowledge to action, therefore HTA can be a tool in the broad challenge of bridging the Know-do (or How to do) gap in health care management (HTAi and INAHTA). With the development of HTA, some Agencies and Institutions started do appear.

INAHTA is the acronym for International Network of Agencies for Health Technology Assessment, a non-profit organization established in 1993 and has now grown to 53 member agencies from 29 countries including North and Latin America, Europe, Africa, Asia, Australia,

[4] http://www.fas.org/ota/technology_assessment_and_congress/houghton/

and New Zealand. All members are non-profit making organizations producing HTA and are linked to regional or national government. Many organizations throughout the world assess healthcare technology. There is an evident need to cooperate and share information from different cultures. INAHTA serves this purpose.[5]

HTAi is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi embraces all stakeholders, including researchers, agencies, policymakers, industry, academia, health service providers, and patients/consumers, and acts as a neutral forum for collaboration and the sharing of information and expertise. With members from 59 countries and six continents, HTAi is a thriving global network. HTAi is actively committed to international collaboration, and has signed formal Memoranda of Understanding with the World Health Organization and the International Network of Agencies for HTA (INAHTA).[6]

HTA can be understood, according to the International Network of Agencies for Health Technology Assessment, as a multidisciplinary field of analysis and decision, which studies the implications of clinical, social, ethical and economic development, dissemination and use of health technologies, without neglecting its political analysis (Goodman 2004).

According to HTAi and INAHTA, HTA is the systematic evaluation of properties, effects or other impacts of health care intervention and may address the direct and intended impacts or consequences of interventions, as well as their indirect and unintended ones. According to these two organizations, the main purpose of HTA is to inform decision making in health care, including decisions made at the individual or patient level, the level of the health care provider or institution, or the regional, national and international levels. HTA is conducted by interdisciplinary groups using explicit analytical frameworks and drawing from a variety of methods.

Initially, HTA was restricted to the assessment of new “technologies”, but over the years its focus has expanded to address questions from all levels of decision making in health care. HTA can assess interventions on four levels: the technology level, the individual / patient level, the population level and the policy level (HTAi and INAHTA). Since HTA focus on health technology, it is important to understand what health technology refers to. According to the HTAi and INAHTA, health care technology refers to drugs, biologics, devices, equipment, supplies, medical and surgical procedures, support systems, and organisational and managerial systems.

HTA addresses the different applications of an intervention, including prevention, screening, diagnosis, treatment and rehabilitation. It is not a one-time evaluation. Rather, it may be applied throughout the lifecycle of a technology, from the design and investigational stages, to standard or established use, and to obsolescence or disposal (HTAi and INAHTA).

[5] From: http://inahta.episerverhotell.net/Home/ (accessed on 25.01.2012)
[6] From: http://www.htai.org/index.php?id=428 (accessed on 25.01.2012)

2.2.2. Technology Life cycle

Since the moment a technology is introduced into the market, until the time that it is replaced or it becomes obsolete, a whole life cycle happens. The natural life-cycle of technologies in health care can be represented in the next figure:

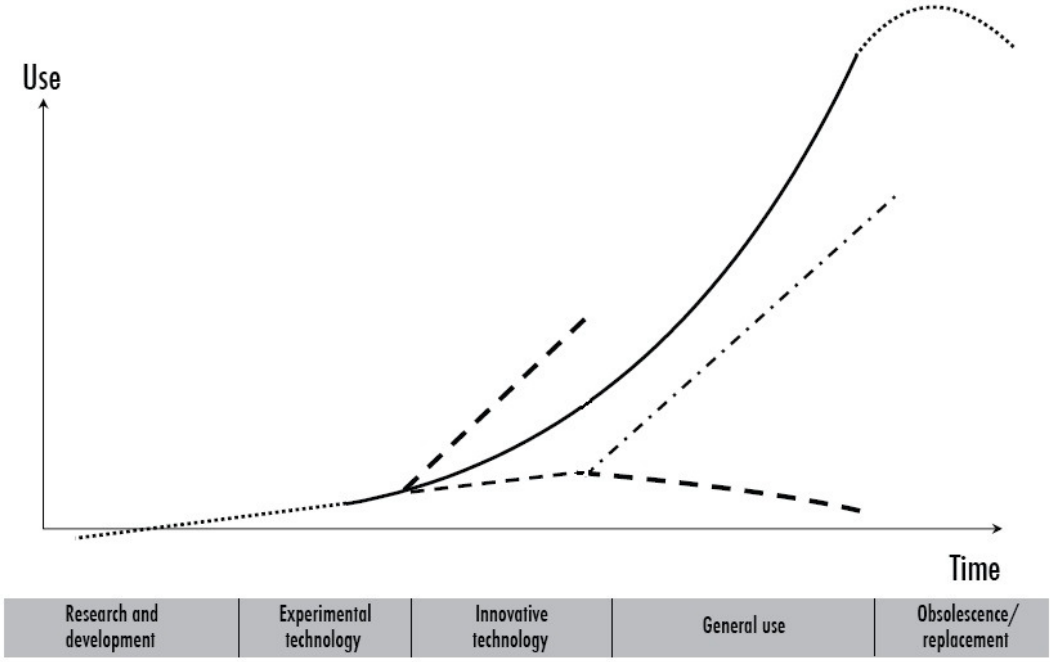


Figure 1 - Diffusion of health technologies
(Source: adopted from WHO, 2011)

The life cycle of a technology begins with the process of Research and Development (some authors name it “Innovation”). The following phase is the phase to experiment the technology or when “early adopters” try to use the new technology, as an experiment, which determines the degree of acceptance of the new technology. According to the World Health Organization (WHO) this phase can also be called “experimental technology” (World Health Organization 2011).

As time goes by and as a reflex of the continued use and possible dissemination, the technology is established and starts to gain confidence by users, in a larger market dimension. This confidence is confirmed with the reimbursement or refund of practice behind the technology. This phase is also a way to strengthen the implicit benefits that technology can bring to society. This phase is called “Innovative technology”, also according to WHO.

Subsequently, it is expected that the market refers to the new technology on a larger scale – “general use” – but that isn’t always the case. Sometimes, it appears that the technology is underused and it is not profitable. There are many reasons for this reality, for example, a miss-location of resources, unequal access to technology, and lack of professionals able to work with technology. Over-estimations of market dimensions or social utility can also explain the under

usage of such technology. Such reality can be applied to any technology in any region or sector, or even in any kind or organization.

The life cycle of a technology ends with the abandonment. At this stage the technology is put aside, because it has become obsolete or ineffective. Or even because companies need to strategically exit the market. That is the “Obsolescence and Replacement” phase, when a specific technology must be replace by a new one (developed by the same company, or by another one).

Taking into account the life cycle of a given technology, TA studies can give a huge contribution in the process of decision making. TA studies should not be made only once during a technology life cycle. Instead, these studies should be carried out along all technology life cycle, as shown in Figure 2. As an example, prior to the incorporation of technology in the health system, an initial assessment process should be made, for instant from an economic point of view (production costs). Other types of studies should also evaluate the advantages and disadvantages, benefits and risks and also the impacts of implementing these new technologies. Taking MRI equipment for example: there are different models of MRI machines, developed by different firms. In the end, some of the MRI characteristics are the same. For instant, the strength of a magnet in an MRI system is rated using a unit of measure known as Tesla (T). The magnets in use today in MRI systems create a magnetic field of 0.5-T to 3T (note that the Earth's magnetic field measures 0.00005T, so this make possible to see how powerful these magnets are).This are the MRI equipment in the market, at present days, however studies are also being made for the market introduction of the 7 and possible 10T.

This first phase of evaluation is limited, since it only allows quantifying the impacts that are observed after the initial diffusion of new technology. TA studies performed at this stage, allow the decision-maker to provide a series of new data that will help him to make the right decision, for example, over the incorporation (or not!) of a certain technology in the market.

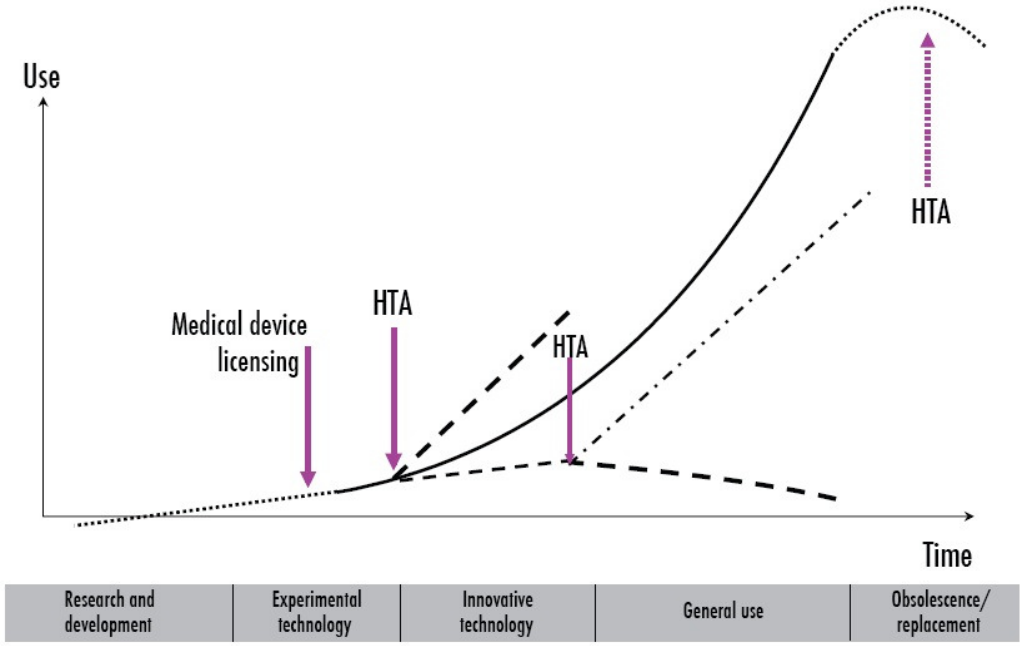


Figure 2 - Health technology assessment and diffusion of health technologies

(Source: WHO, 2011)

When a new medical technology is introduced in the market, it becomes clear that there is a need to assess the problems that may emerge, with such introduction. Usually, when it happens, hospitals or health institutions are not quite ready to handle this issue. That is why assessment teams are needed and put together, to develop HTA reports on this matter.

The introduction of MRI into clinical practice was a clear example of this matter. We can take as an example the case of Switzerland. In Chrzanowski and Gutzwiller paper we can realize that, to handle with the problems raised by the introduction of new medical technologies, two non-governmental institutions were created: The Swiss Hospital and Public Health Institute (SHI) and the Association of Swiss Hospitals (VESKA). This new institutions were called to study special health emerging problems, and among them, new medical technology (cf. Chrzanowski and Gutzwiller 1986).

A panel of experts (including representatives of diagnostic radiology, biochemistry, medical physics, social medicine and epidemiology, universities, insures companies, etc.) prepared a report on MRI, where it was established the need for this kind of technology in the country and the number of sites of MRI systems in the capital, running and unitary costs on this diagnostic procedure were also estimated. This kind of HTA study helped planning investments and also helped to deal with reimbursements and other issues on health care policy, so new recommendations start to appear.

If we now think in the final phase of the life cycle of technology, the decision-makers (further on designated as DM) have, once more, to make a decision concerning the abandon or replacement of a certain technology. HTA reports can be helpful when this kind of decision has to me made.

As we said before, health technology assessment should be a practice along health technology life cycle, since many problems can be defined along this life cycle. In their paper, Chrzanowski and Gutzwiller listed some problems along technology health cycle: funding, reliability, safety, control of standards, etc., that we now schematize in Table 1 (cf. Chrzanowski and Gutzwiller 1986).

Stages	Problems
Research and development	- Funding
	- Reliability
Experimental technology	- Safety
	- Efficacy
Innovative technology	- Safety
	- Effectiveness
	- Cost
	- Initial Evaluation
General use	- Long-term side-effects
	- Outcome
	- Efficiency
	- Standardization and Stability
	- Reimbursement
	- Complete Evaluation
Obsolescence / replacement	- Control of Standards

	- Comparison with emerging technologies - Funding of modification - Replacement

Table 1 – Stages in the diffusion of health technologies and the occurrence of some problems

On one hand, the political decisions made and based on HTA reports should take into account scientific evidence, linking efforts between the technical, economic and political dimensions, using a participatory vision, so that it can be translated in the best possible decision (cf. Novaes 2006). On the other hand, the success of such decisions depend critically on the skills of the researcher to convey wisdom and confidence in applying rules of argumentation (cf. Armin Grunwald 2007), thus it is of utmost importance to identify all potential decision makers involved in technology assessment process.

For this matter, the identification of DM (also referred as stakeholders or actors), activities and priority settings for HTA in Portugal, is needed on a national level. Following the example of other countries who already made this data collection, as for example, Netherlands (cf. Oortwijn et al. 1999), US (cf. Perry and Thamer 1997), France (cf. Stephan 1988), lessons can be learned from others and experiences studied. With the purpose of understanding the need for co-ordinated efforts in this area, different further on designated as DM can become and work as team, and also some sharing experiences can be promoted. This data gathering is very important for a balanced TA process.

2.2.3. Europe's interest in Health Technology Assessment

Meanwhile, in Europe, TA issues were also a subject of interest. OECD published several papers and books on TA between 1974 and 1983, and a numerous organizations have benefited from TA discussion, carried out TA-like studies and developed TA-like procedures. An inventory of these experiments was drawn up by the Dutch Organization for Applied Scientific Research (TNO). Based on this inventory the authors show that a new wave of TA institutionalization has occurred in Europe. Different forms of TA institutionalization are presented in which choices have to be made with regard to the political, executive and scientific organization of TA. How and when these choices are made depends on the constitutional and political structure and traditions of the particular country. Therefore, four main variants emerged: governmental TA institutes, parliamentary TA institutes, independent TA institute and combined forms of institutionalization (Tuininga 1988).

One special area subject of TA was health care. In fact, one of the first reports from OTA was related to TC scan. It was the beginning of HTA. The European interest in HTA dated back to the late 1970's, with the growing interest on economic aspects of health technologies (Johnson, 2002 cited in Velasco-Garrido and Busse 2005).

Regarding the scope and types of assessment, according to Garrido et al. (2008) in the first year of HTA in Europe, the few existing agencies concentrated mainly, on the assessment of procedures as medical devices. As an example, we can find pre operative diagnostic routines

and their use in Sweden assessment report by SBU[7], as their first HTA report in 1989 (Arvidsson et al. 1989 cited in Garrido et al. 2008).

Another example can be identified in Catalan Agency for Health Technology Assessment and Research[8] who, in the first report evaluated the procedure for ambulatory surgery (Espiràs et al., 1992 in Garrido et al. 2008).

As health medicine and the health care procedures evolved, so does the scope of HTA. Nowadays we can assist to a variety of assessments, that include medicines, procedures, devices, interventions... Not only the scope, but the type of assessment have also evolved. We have assisted in the begining (before formal institutionalization of HTA) to capital – intensive technologies and costly pharmaceuticals assessments (cf. Banta and Jonsson, 2006 cited in Garrido et al. 2008). To clinical aspects of technologies that dominate the majority of assessments (Garrido et al. 2008). However, organizational and societal issues have not generally been assessed with the same depth (Means et al. 2000; Draborg et al. 2005 cited in Garrido et al. 2008).

2.2.3. Health Technology Assessment in Portugal

Regarding the development of HTA programmes in the European Union, Banta and Oortwijn (2001) established an overview of HTA activities in 16 European countries. These programmes have been established during the last decade or so. According to their paper, the countries that began to assess health technologies in the early 1970's and that can be considered leaders are Sweden and Denmark, and also Spanish province of Catalonia which established a committee on health technologies in 1984. Some countries established or designated national programmes to become involved in HTA, like Sweden (1987), France (1990), the United Kingdom (1990), Spain (1994), Finland (1995) and Denmark (1997). Others, like Portugal, when regarding HTA, just made, so far, some studies and analysis in the field. However, it is possible to assist to a growing interest in this matter, as the discussion of establishing a national HTA agency is taken into account (David Banta and Oortwijn 2001)

In the search made, only one article addressed directly the relation between HTA and Portugal, as the main focus. It was published in the year 2000. In this paper, we can read that "Health technology assessment (HTA) is not very developed in Portugal", although "there is presently a growing interest in HTA in Portugal". This statement was said by Pinto, Ramos and Pereira on their paper in the year 2000. This paper reports on the status of HTA in Portugal. Their position was corroborated by the intentions of the Ministry of Health, who in the future was planning "the

[7] SBU is the Swedish acronym for the Swedish Council on Technology Assessment in Health Care. established in 1987 by the Swedish Government to answer these and similar questions on behalf of the healthcare sector. Initially, SBU was an agency under the Swedish Government Offices.
In 1992, SBU was commissioned as an independent public authority for the critical evaluation of methods used to prevent, diagnose, and treat health problems. (in: http://www.sbu.se)

[8] CAHTA was the Catalan acronym for Catalan Agency for Health Technology Assessment and Research.The former CAHTA broadens its functions and it is now denominated Catalan Agency for Health Information, Assessment and Quality (CAHIAQ). The CAHIAQ has now the mission of generating relevant knowledge to contribute to the improvement of the quality, safety and sustainability of the Catalan Health Care System and thus easing the decision-making process for citizens and health care managers and professionals.(in: http://www.gencat.cat)

creation of a national (or regional) agency responsible for HTA, where economic evaluation studies will be a fundamental part of the assessment" (Pinto, Ramos, and Pereira 2000).

Eleven years went by and the reality stays the same. The main idea persists... "It is critical to move forward towards the creation of a national agency of health technologies assessment, independent of political power, with technical and scientific autonomy, appropriate and highly qualified. This entity, in line with best international practices, would have the best conditions to assess and for innovation involving the parameters of the cost-effectiveness the principle of cost-opportunity and taking into account the limited resources and the need to qualify the choices"[9], states Adalberto Campo Fernandes, on the chapter "The health policies" of his new book (Fernandes 2011). This book gathers three essays from three different authors and by that, three different perspectives for the health future in Portugal.

Economic evaluation of health technologies is not done in a systematic, integrated, coherent manner. There are economic evaluation studies in areas such as pharmaceuticals, heavy equipment, and medical devices, but in practice they are very few. Policy decisions are not based on systematic assessments. In the pharmaceutical area, criteria for exclusion of reimbursement for a new drug are excessive cost and lack of evidence of therapeutic efficacy in comparison with similar reimbursed drugs. Excessive cost is determined by comparing the price of the new drug to the price of the cheapest similar reimbursed drug (excluding generics). In fact, this procedure involves a comparative analysis of therapeutics, and identifies, measures, and compares costs and effects of two alternatives. This is one of the few areas where such evaluation is carried out in Portugal (Pinto, Ramos, and Pereira 2000).

According to the same authors, "The field of HTA is only now emerging in Portugal. Economic evaluations in areas such as pharmaceuticals, heavy equipment, and medical devices have begun to be carried out in the past few years, but their impact on policy is uncertain."

In a more recent report concerning Portugal health system, by the European Observatory on Health Systems and Policies and Nova School of Business and Economics, it is stat that Portugal does not have a tradition of HTA, with the exception of pharmaceutical products.. Since 1988 the Ministry of Health has authorized the procurement and installation of expensive medical technologies in the public and private sectors. In 1995, new legislation lifted the restrictions on computerized (axial) tomography (CT) and magnetic resonance imaging (MRI) scanners. There are currently no effective methods for regulating the distribution of health equipment in the private sector. Most expensive medical equipment (67%) is located in the private sector, which is more flexible and innovative and therefore outstrips the public sector in the acquisition of high-technology equipment. Hospitals contract with private clinics for the use of equipment, providing a strong incentive for this provision pattern to continue (Barros, Machado, and Simoes 2011).

According to the same authors, medical devices are regulated by law – Decree nº 145 / 2009, which determines that the INFARMED (National Authority of Medicines and Health Products) is the entity responsible for the surveillance of all medical devices. This Law-Decree establishes

[9] In the original: "é fundamental avançar no sentido da criação de uma agência nacional de avaliação de tecnologias da saúde, independente do poder político, com autonomia técnica e científica, idónea e altamente qualificada. Esta entidade, em alinhamento com as melhores prácticas internacionais, teria as melhores condições para avaliar a inovação associando aos parâmetros de custo-efectividade o princpio de custo-oportunidade e tendo em conta a limitação de recursos e a necessidade de qualificar as escolhas."

rules about R&D, manufacturing, sales, entry, surveillance and advertising. This document adopts the EU Directive nº 2007 / 47 / CE to Portuguese legislation.

In the some report, the authors conclude that, currently there is no economic evaluation applied to medical devices and mainly there is clearly room for further efficiency gains in the delivery of health care in Portugal, where the role of HTA is currently limited to pharmaceutical products.

2.3. Decision Making

This chapter aims to give a general elucidation on decision-making matters. A brief introduction of decision-making general aspects will be defined, followed by the competences necessary to be able to conduct a good decision-making process.

2.3.1. Competences for Decision-Making

The decision maker needs to evaluate the effectiveness and efficiency of a given technology, with variable costs and limited resources available during the decision-making process for the acquisition of such technologies. In health area, prior to taking any decision on the technology assessment, the decision maker must take into consideration some issues such as:

- From the technologies available in the market, which ones can meet the needs of the population (in general)?

- Will the technologies - identified as necessary for the general population - generate the expected benefits?

- What are the health gains for the population, with the implementation of the technology?

- Is there enough resources (financial, economic, human...) available and will they be sufficient to provide and maintain the technology (equipment, software, protocols, etc.) to all who eventually be need it?

- Do social and ethical issues have been taken into account, when technological resources are being allocated? (population needs, geographical localization for the new equipments, existing nearby equipments for example)

To answer to these questions, decision makers need to support their answers in HTA studies, since those studies provide a set of HTA information, reliable and synthesized on the effect and costs of health technology.

According to the "White Paper on Education and Training" of the European Commission there are some factors that have boosted the possibilities of access the information and knowledge for people, but simultaneously as a consequence, led to changes in work organization and skills learned. These factors relate to the internationalization of trade, the global context of technology and above all the emergence of the information society (European Union 1995).

This reality can be seen in the area of radiology, specifically the MRI, because it is an area of constant and rapid technological change, since this is an increasingly complex system at various levels, which requires constant updating knowledge, a therefore skills, by the professionals who deal with it and work with it.

The "White Paper on Education and Training" also makes a remark, as a consequence of this new reality, some people go through situations of exclusion (European Commission 1995). For this not to happen, in a Radiology Department, in the Magnetic Resonance area (and beyond!) professionals must keep their knowledge updated, since at present it is ease of access to information so that they won't be excluded from dealing with this imaging technique. But it is not enough to study and develop these skills. There are other skills that should be developed so that professionals do not take the risk of being (by themselves or others) alienated from this technique. Thus, after the identification of key DM involved, it becomes interesting to understand and identify the skills that this decision makers hold to be considerate as such.

According to Maia e Moniz, "competence" can be defined as a set of skills, abilities, related knowledge and attributes that enable an individual to perform a task or an activity within the course of their work (Maia and Moniz 2011). In the same way, the International Labour Organization - ILO definition refers to competence as an "ability to articulate and mobilize the intellectual and emotional conditions in terms of knowledge, skills, attitudes and practices necessary to perform a particular function or activity, in an efficient, effective and creative way, according to the nature of work " (Organização Internacional do Trabalho 2002). The ILO also refers that competence must be understood as "the ability to mobilize acquired knowledge and emotions to make decisions, to solve new problems and building work in a creative way "since the knowledge of today are in line with reality not mass production (as opposed to the origin of production Taylorism and Fordism honoured) and flexible work (Organização International do Trabalho 1999).

In health systems, the World Health Organization defines competence as "capabilities, skills, knowledge, behaviours and attitudes that are fundamental to the achievement of desired results and therefore performance at work " (World Health Organization 2005).

Competencies are operationalized at the level of "Knowledge." The knowledge can be described as: knowledge *per se*, how to do, how to be and how to learn, which correspond respectively to the skills acquired in training, the skills acquired in the performance of the profession, to attitudes that the professional assume in his daily life and cognitive abilities that allow to learn, think and process information. The relationship between the different "knowledge" was sketched in Figure 3.

Figure 3 - Schematization between the different "knowledge" and Skills
(Source: Adapted from UNIDO 2002)

These knowledge are closely related to each other, forming a set of knowledge, that the professional will acquire and develop throughout his activities, so throughout his professional life, as he modifies his competences.

Despite the methodology used in HTA, the decision-makers involved, or the types of technologies assessed, a certain degree of uncertainty will always persist in the decision process. It is up to the decision-maker to accept the existence of this uncertainty and the level of arbitrariness in the choices made (cf. Stephan 1988). However, technology assessment studies tend to reduce uncertainty in decision-making process, by providing full evidenced information on a given matter. But they aren't one hundred per cent uncertainty free.

3. Portuguese National Health System

In this chapter is intended to make a framework of the Portuguese Health System, aiming to have a better framework for characterizing the distribution of MRI technology in the country. It is on the best interest to understand who makes up the system - Health Stakeholders - in what way and how does it relates to other entities.

3.1. NHS Characterization

In the paper “Health Technology in Portugal”, Pinto, Ramos and Pereira, make a very explicit resume regarding Portuguese NHS. According to the authors, the Parliament determines the total budget of the NHS. The Minister of Health is responsible for the definition of the national health policy and the promotion and surveillance of its execution. The Ministry of Health is responsible for regulating, coordinating, planning, evaluating, and inspecting the services of the NHS. Responsibility for the functioning, organization, and management of the NHS is shared by the Ministry of Health and five Regional Health Authorities. The Regional Health Authorities are responsible for the planning and distribution of resources and the coordination and evaluation of hospital and health centre activities in their regions. The health system includes the NHS and all the public entities with activities in health promotion, prevention, and treatment of disease, as well as private entities and professionals that contract with the NHS to provide health services. The NHS includes all the public healthcare providers that depend on the Ministry of Health (Pinto, Ramos and Pereira 2000).

The 1979 legislation stated that the private sector should complement the public sector by providing health care in areas that could not be served by the public sector. NHS patients referred to private healthcare providers normally do not pay for the service delivered. Providers are reimbursed directly by the NHS.

3.2. Health Stakeholders and the Administration of the System

Before we can understand the process of decision making it is important that the decision - makers (or stakeholders) can be identified.

The identification of DM (also referred as stakeholders or actors), activities and priority settings for HTA in Portugal, is needed on a national level. Following the example of other countries who already made this data collection, as for example, Netherlands (cf. Oortwijn et al. 1999), US (cf. Perry and Thamer 1997), France (cf. Stephan 1988), lessons can be learned from others and experiences studied. With the purpose of understanding the need for co-ordinated efforts in this area, different DM can become and work as team, and also some sharing experiences can be promoted. This data gathering is very important for a balanced TA process.

A recent report from Deloitte, states that primary health care institutions as well as secondary and continued care institutions are at the present the NHS basis as well as of the all health care system, cohabiting with the private and social health entities. In a very explicit way, Deloitte represented those hey stakeholders as we can see in Figure 4 (Deloittte 2011):

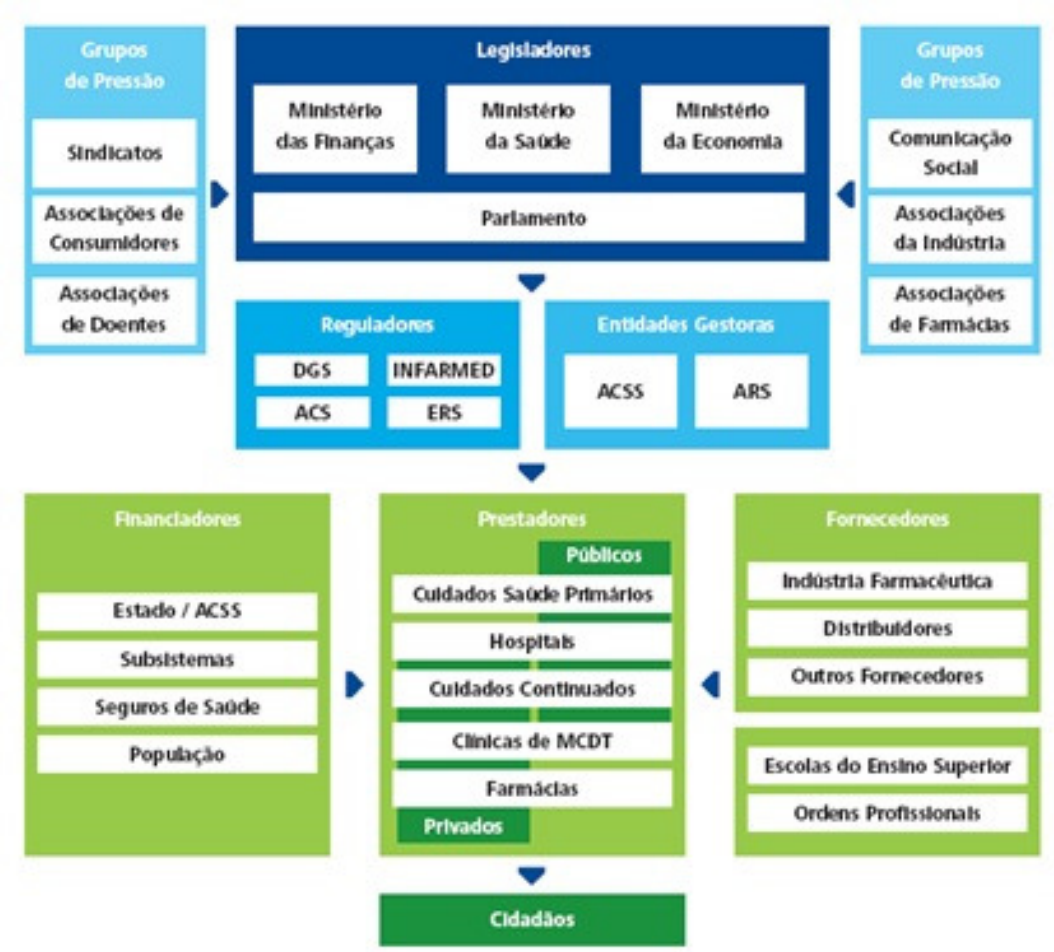


Figure 4 - Key Stakeholders in the Portuguese health sector
(Source: Delloitte, 2011)

4. Investigation Context - The MRI

In 1946, Block and Purcell developed the principles of MRI, which earned them the award of the Nobel Prize for Physics in 1952. Later in 1951, Gadillard demonstrated that it was potentially possible to obtain spatial locations with MRI. In 1975, the first prototype of a magnet for commercial purposes is developed, and from 1980 to 83 the first publications of clinical studies appeared (Tavares 1999). MRI differs from other imaging techniques, since:

- allows axial, coronal and sagittal imaging;
- has a high sensitivity to the movement of fluids (including blood and cerebrospinal fluid);
- does not use x-ray radiation to obtain images, since tissue images are based on their own physical and biochemical properties;
- there is some ease of observation of tissue surrounded by bony structures (particularly in the posterior fossa and spinal cord). (Tavares, 1999)

In terms of hardware, the basic hardware components of all MRI systems are the magnet, producing a stable and very intense magnetic field, the gradient coils, creating a variable field

and radio frequency (RF) coils which are used to transmit energy and to encode spatial positioning. A computer controls the MRI scanning operation and processes the information.

The range of used field strengths for medical imaging is from 0.15 to 3T. The open MRI magnets have usually field strength in the range 0.2 T to 0.35T. The higher field MRI devices are commonly solenoid with short bore superconducting magnets, which provide homogeneous fields of high stability. There are these different types of magnets: resistive magnet, permanent magnet and superconducting magnet.

The majority of superconductive magnets are based on niobium-titanium (NbTi) alloys, which are very reliable and require extremely uniform fields and extreme stability over time, but require a liquid helium cryogenic system to keep the conductors at approximately 4.2 Kelvin (-268.8 Celsius). To maintain this temperature the magnet is enclosed and cooled by a cryogen containing liquid helium (sometimes also nitrogen).

The gradient coils are required to produce a linear variation in field along one direction, and to have high efficiency, low inductance and low resistance, in order to minimize the current requirements and heat deposition. A Maxwell coil usually produces linear variation in field along the z-axis; in the other two axes it is best done using a saddle coil, such as the Golay coil.

The radio frequency coils used to excite the nuclei fall into two main categories; surface coils and volume coils. The essential element for spatial encoding, the gradient coil sub-system of the MRI scanner is responsible for the encoding of specialized contrast such as flow information, diffusion information, and modulation of magnetization for spatial tagging. An analogue to digital converter turns the nuclear magnetic resonance signal to a digital signal[10]. The digital signal is then sent to an image processor for Fourier transformation and the image of the MRI scan is displayed on a monitor.

However, this technique presents some disadvantages. Due to the high magnetic field it has and the size of the magnet tunnel, some patients are contra indicated to perform such exam in particular, patients with pacemakers, metallic prostheses not compatible, claustrophobic patients, patients with morbid obesity.

It is not an easy task, to assess magnetic resonance imaging since it includes aspects of epidemiology, bio-statistics, clinical efficacy determination, outcomes assessment and knowledge of the technical and medical bases of imaging method (Thornbury and Fryback 1992). There are too many different knowledge fields to tackle. Also that means such assessment process should always involve different scientific and technical competences.

In 1997, Fireberg et al. proposed a hierarchical conceptual framework for use in the evaluation and comparison of diagnostic imaging for imaging tests. According to Gazelle and colleagues (cf. Gazelle et al. 2005), this approach was later adopted and modified by others, such as Fryback (1983), Fryback et al. (1991), Dixon (1997) and Hunink (1998). This model however, wasn't new, since it has been described In the early 1970's parts of the levels began to de described and its earliest form was published in a paper by Fryback in 1983 (Thornbury and Fryback 1992). Such model also can serve as a structure for a design of scientific research that can be achieved to assess the impact and usefulness of MR imaging. In a simple way, this hierarchical model, takes into account six levels of efficacy according to Fryback and Thornbury (1992):

[10] From: http://www.mr-tip.com/serv1.php?type=dev

1. Technical
2. Diagnostic accuracy
3. Diagnostic thinking
4. Therapeutic
5. Patient outcome
6. Societal.

This kind of hierarchical model can be applied, for example, in the assessment of the technology for functional imaging cancer (cf. Laking, Price, and Sculpher 2002). Manufacturers, clinicians, patients, therapeutic and diagnosis technicians, hospital managers, government leaders, among others, either in the public or private sector, are increasingly demanding for the sustained demand of information to support their decisions. Such decisions can cover aspects as if a certain technology can be developed or how it will be done, or even whether a technology should or should not enter the market, or even if a certain technology should be acquire, transferred and/or used.

This demand is well implied in the growth and development of HTA. Regarding MRI technology, HTA can be used in different types of health care decision-making as one or more properties, impacts or other attributes of this health care technology or its application can be assessed. In general, aspects like: safety, efficacy and /or effectiveness, technical properties, economic attributes or impacts and social, legal, ethical or political implications can be also assessed.

In an attempt to frame MRI reality in Portugal context we are able to see that the lack of planning rules has allowed a gap to grow between public and private investments. The western area of Portugal is better equipped with doctors, health institutions, and equipment than other areas of the country. High-technology equipment is concentrated in the larger cities. The private sector is more flexible and prone to innovation. It is the leader in high technology. About 67% of larger and more expensive medical equipment is found in the private sector. For example, 1,628 of the 1,944 haemodialysis machines, 22 of the 27 MRI devices, 83 of the 122 CT scanners, and 7 of the 12 lithotripters are in the private sector. Investments in medical equipment were limited until about 10 years ago. During the last 10 years, investment has increased. Of all high-technology equipment currently available in the country, 21% was purchased in the last 5 years (Pinto, Ramos and Pereira 2000).

5. Research Methodology

For this study, It will be take into account the population formed by the DM, regarding TA decision-making, in MRI context. By setting the sample it is not intended to obtain a statistically representative one, but rather a set of personalities who are "socially significant" that allow a diversity of opinions, according to Guerra (cf. Guerra 2006). Thus, the sample is selected by convenience and according to a set of inclusion and exclusion criteria, to encompass and have represented all DM involved.

In order to frame the whole issue, as an instrument of data gathering, we will use individual interviews, semi-structured. According to Marconi and Lakatos (cf. Lakatos and Marconi 2008),

in a semi-structured interview, it is given some freedom to the interviewee so that he can develop each situation in the direction that he feels most appropriate. The questions are, in general open, so that the interviewee can respond according to his opinions, values and references. The use of this type of research technique is most appropriate because we want to extract qualitative information that allows us to understand the complexity of decision-making processes, associated with the use of MR technology and its development.
The questionnaire will also be used as a tool for collecting data. However this use will only serve to collect quantitative data on the technologies and processes used in management of technical resources in the area of radiology. It will be built a Guide for the interview so that it can be structured and allow some guidance to the researcher, according to the direction of the responses given, to conduct the interview in order to achieve the proposed objectives. Briefly, there Guide of the interview will consist of 3 main parts:

I – will address issues related to the interviewee, to allow further social-demographic characterization;

II – will consist of questions that allow the gathering of information relating to issues under discussion (will be covered four types of knowledge identified in Figure 3);

III –will include questions that allow making a summary of the interview, and also allowing complete it, drawing some conclusions.

The data obtained will be of qualitative nature and therefore require an analysis of their own, for that content analysis will be the choice, because through it, the investigator has a great capacity for interpretation and inference, although running the risks inherent in such research. In this type of analysis the framework previously established by the investigator will be confronted with the empirical material previously gathered (cf. Guerra 2006).

Within the content analysis, the researcher will analyse the data, through categorical analysis, which according to Bardin (cf. Bardin 2009), aims to take into account the totality of a "text", which is then subjected to a classification and a census, according the frequency of presence (or absence) of items of meaning. The quantitative analysis will also be held.

5.1. Framework

The methodology described is intended to answer the following questions:

Q1 In HTA, which decision-makers are involved and what are their points of views?

Q2 What skills should the decision-makers possess, in the process of decision making during the HTA?

Q3 What procedures should be taken into account in the decision-making process?

Q4 What indicators are present in decision-making process? What is its priority?

Q5 What are the factors that may influence the decision-making process from each decision-maker point of view?

Q6 Is there a competitive advantage for HTA, in equipment acquisition?

This paper purposes a framework of Technology Governance to study the HTA influence in health care, giving as an example the Radiology Department, more specifically the MRI Unit. To accomplish the intended of this work, a list of hypothesis was formulated. The analysis of responses intended as a framework to accept or refute the research hypotheses:

H1 The HTA in Radiology allows the identification of all decision makers (stakeholders) involved in decision making as well as their points of view. These are the decision makers who could be members of evaluation panels, as well as participants in future workshops on Radiology. The identification of decision makers is a crucial factor, in a successful management model, for this technology.

H2 The more participative the decision-making process is, the more efficient the model of technology management becomes.

H3 The existence of HTA programs for the acquisition of radiological equipment provides greater health gains for patients.

H4 The HTA in Radiology helps to reduce conditions of uncertainty. This process promotes quantity and quality HTA information and therefore tends to reduce the uncertainty related to the choice to be made (purchase of equipment, introduction or modification of a protocol, terms of use, request for replacement, etc.) and decreases the chance of conflict over the decision.

H5 The presence of HTA programs in health for Radiology, lead to decreased costs in general, since the process of decision making is based on evidence (and its management more efficient?).

It is hypothesized that HTA can have a major impact on the process of decision-making, by affecting DM points of view. As a consequence health gains will arise (see Figure 5)

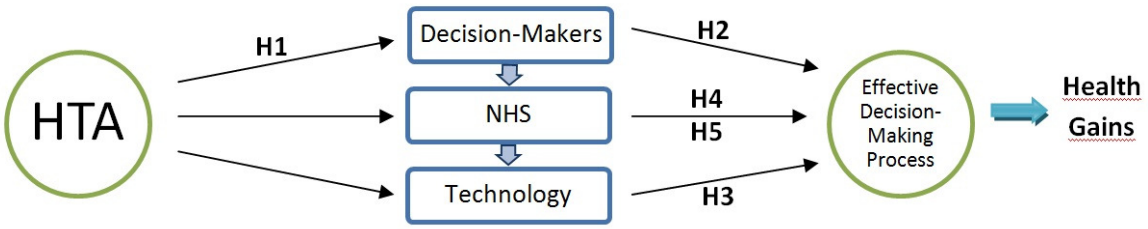


Figure 5 - Relationship between the hypothesis

The conceptual framework is represented on Figure 6.

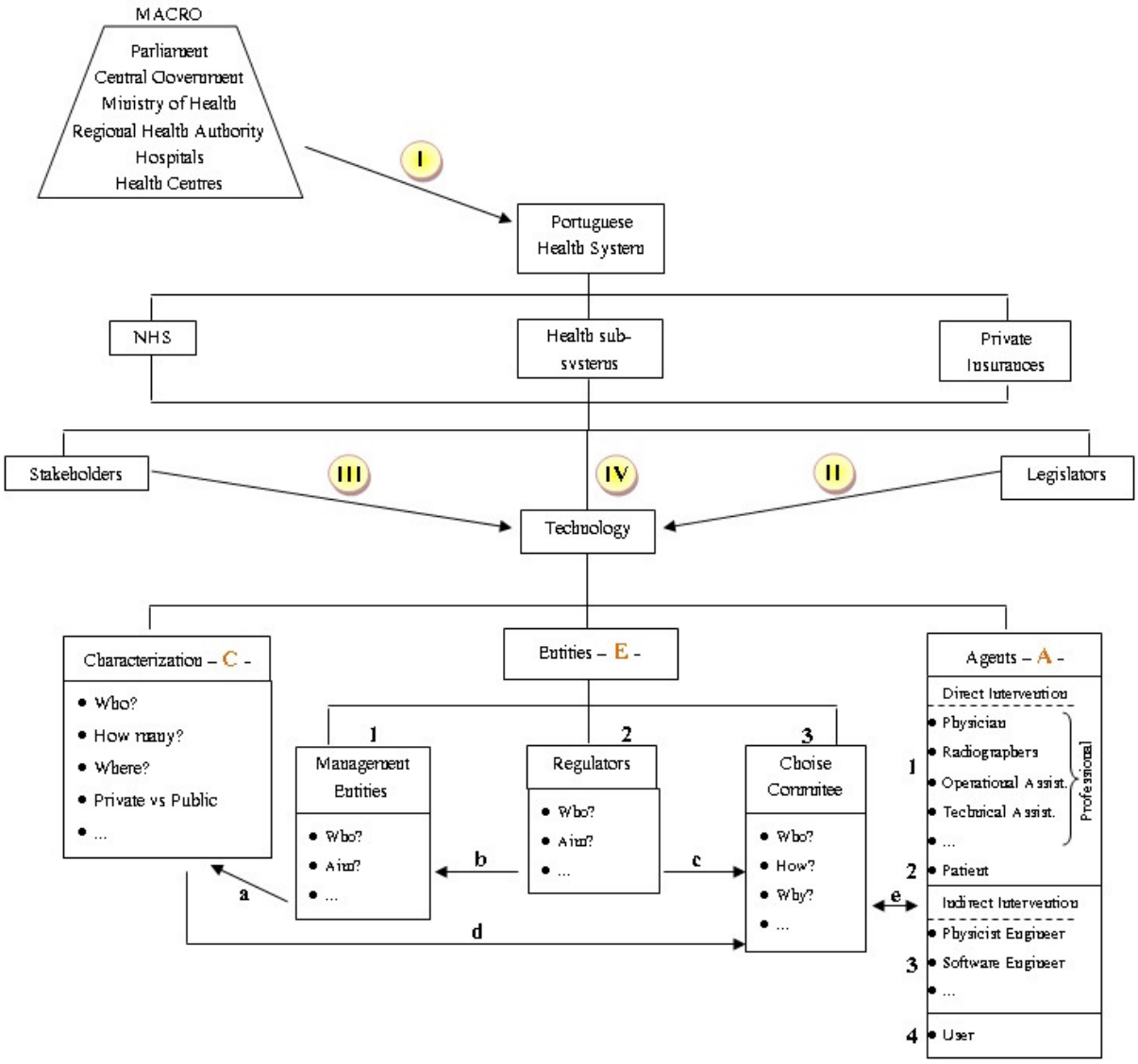


Figure 6 - Conceptual Framework

The research question previously identified can now be related to some part in the conceptual framework:

- Q1 - A1, A2, A3
  E1, E2, E3, …
- Q2 - those identified in Q1
- Q3 - a, b, c, d, e
- Q4 - C, A
- Q5 - I, II, III, IV

Further research will be conducted complete, test and validate the proposed framework on Technology Governance in Radiology.

5.2. MRI Equipments

In order to study the MRI equipment's in Portugal, an attempted to survey the state of the art regarding the existence of this equipment was made. The first step consisted on listing the firms that represent this equipment in Portugal. As a result four firms were identified as the companies competing in MRI technology marketplace:

- Philips
- Siemens
- General-Electric (GE)
- Toshiba

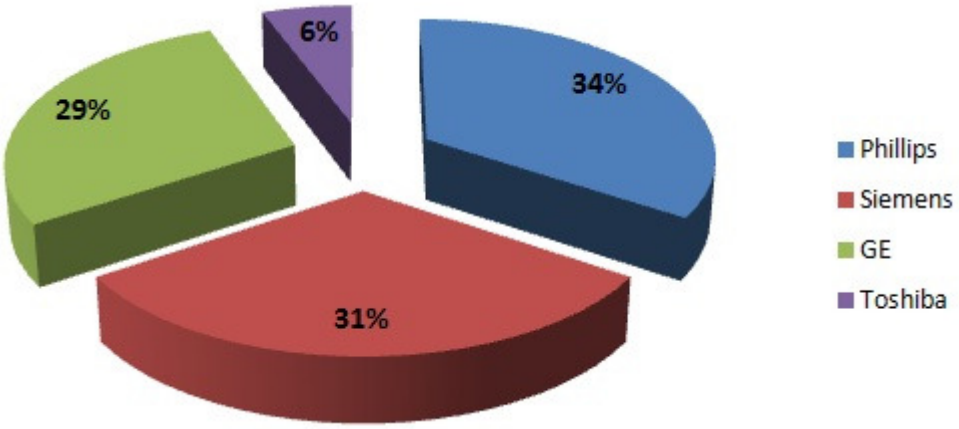
An e-mail was sent to the commercial department asking the total of equipment's represented by each firm and in which sector were they: public or private health sector. As a result the data gathered still need confirmation, since the companies gave a non-confirmed answer. GE chose not to respond claiming confidentiality of data.

To overcome the lack of data, a desk research was made combining internet data from clinics, hospitals and MRI equipment's licensed by the General Directorate of Health (DGS). As a result of this research there are, regardless of the equipment model (see Table 2) in total, there are 105 MRI equipments in Portugal, distributed mostly on the private sector. Philips is the leading firm in terms of representation.

Firm	Sector					
	Public		Private		Total	
	nº	%	nº	%	nº	%
Phillips	9	8,57	27	25,71	36	61,71
Siemens	11	10,47	22	20,95	33	53,95
GE	--	--	--	--	30	28,57
Toshiba	0	0	6	5,71	6	5,71
Total	20	20	55	55	105	100

Table 2 - MRI equipment distribution in Portugal, by firm and sector

Because the GE data is missing, regarding the localization of the MRI equipment (private or public sector) it was only possible to analyse in a graphic the weight of each firm in the market (Graphic 1):



Graphic 1 - MRI equipment distribution by firm

In an attempt to study their localizations geographical, using the some data gather (but excluding GE information), an attempt for a visual layout was made on Figure 7:

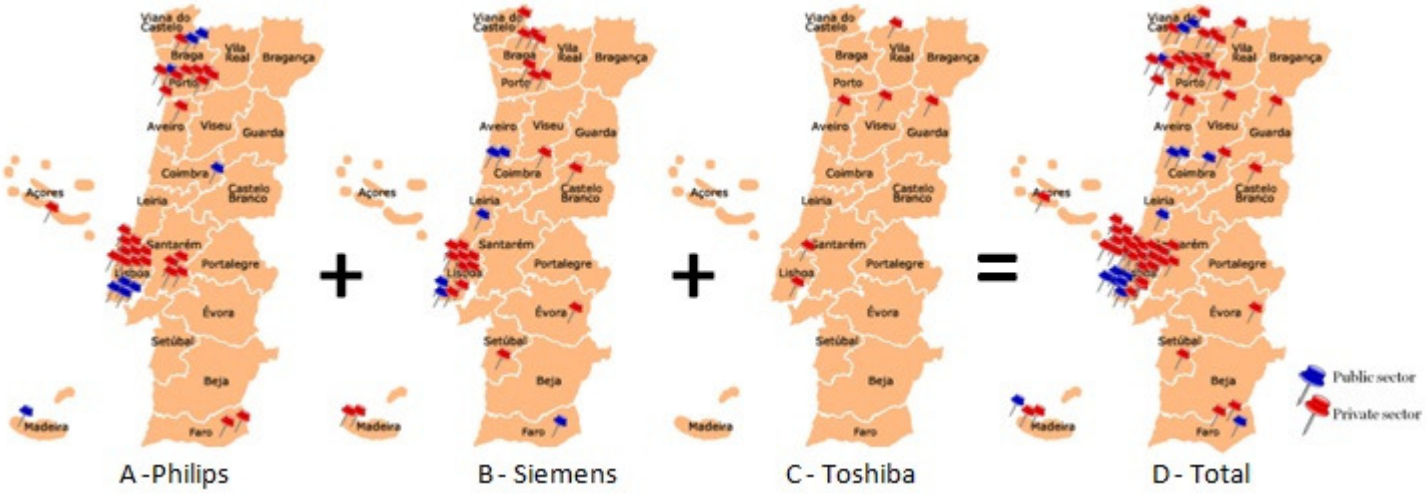


Figure 7 - Total geographic distribution of MRI equipment, by firm and sector

When analysing the D distribution (Total) it becomes clear that there is a concentration of these type of equipment in the north and centre of Portugal, and very few are in the interior.
Once again it is emphasized the need to deepen and confirm these data.

5.3. Identifying and Approaching Decision-Makers

If we considered the general National Health System (NHS) and take into account only the Radiology Department (taking MRI as a technology example) we can identify, in a macro view some of the DM as well as some of their relationships. These are represented on Figure 8

Figure 8 - Macro representation of the stakeholders and some of their relationships

It is considered “patient” every one that goes to a Radiology Department to make an exam. The community it is also considered because we can’t ignore that they have representatives just to speak from them, whenever they are questioned and put at risk regarding health.

We have also the MRI equipment producers and the pharmaceutical that are related with the development and production of different technologies complementary to MRI such as contrast media. The dealers and the MRI equipment representatives are also decision-makers as well as different material suppliers to the Radiology Department. Employees are considered all professionals that work in Radiology, especially in the MRI unit. We have also the government, who make the laws concerning health protection, technology regulations, equipment’s supervision, etc...

Going on a more micro level, the DM identification and characterization is modified depending on the scenario that is being targeted by the study. We will take as an example, an examination being done at a Radiology Department, represented in the form of a flowchart (Figure 9):

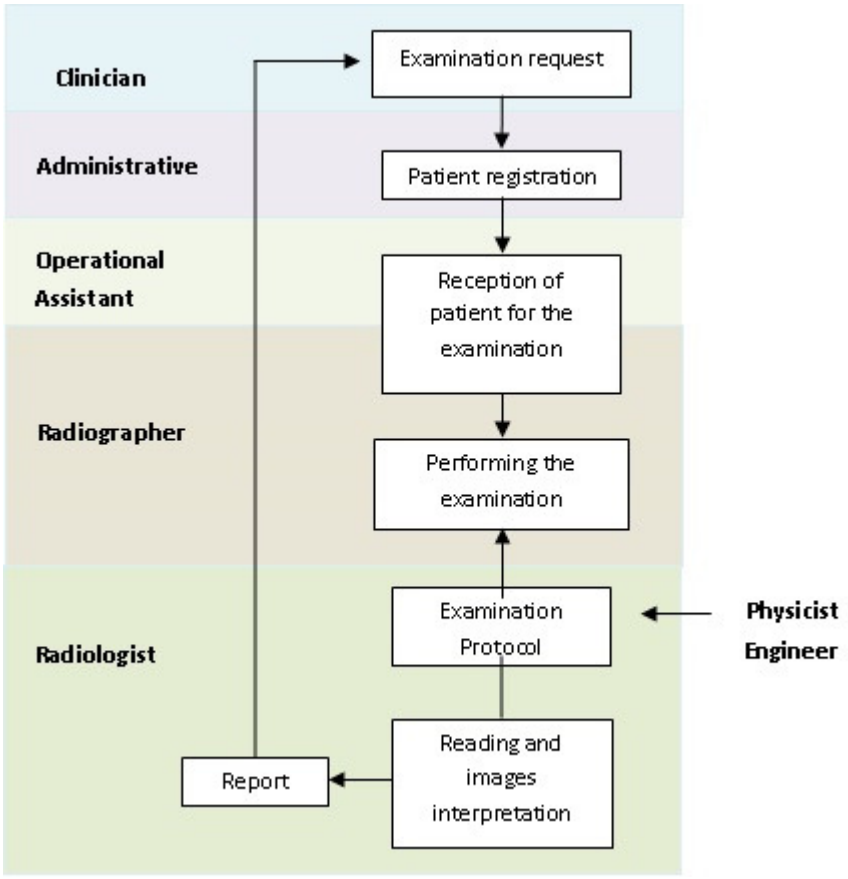


Figure 9 - Flowchart for performing an examination, on a Radiology Department

By analysing the flowchart, we can identify six DM: the Clinician who makes the request for the examination, the Administrative (in Radiology Department) that receives the request for the examination and shall enter it or will schedule of the same, the Operational Assistant that guides the patient from the waiting room to the exam room, where the Radiographer then welcomes him and guides him through the exam. Under the guidance (or not) of the Radiologist and the support from the Physician Engineering, the Radiographer performs the exam. The exam will then follow one of two ways: going straight to the Clinician who requested it or be interpreted and reported by the Radiologist before being sent to the Clinician.
In resume, the DM identified in the example were:

- Clinician
- Administrative
- Operational Assistant
- Radiographer
- Radiologist
- Physician Engineering

If we make the exercise and try to identify the DM involved in Portuguese TA studies, we realise that they are essentially health professionals, specially clinicians, whom most of the time have the last word regarding decision about the adoption (or not) of new technologies. This opinion is shared by Silva and colleagues who also express that due to the lack of knowledge about

economic evaluation techniques, these clinicians (who haven't had health economics as their diploma studies) have some difficulties in having economic studies into account (cf. Silva et al. 2008).

It is important to make a stakeholder analysis. This analysis will be performed in the future. According to the World Health Organization, the Stakeholders Analysis is a technique used to identify and assess the importance of key people, groups of people and institutions (World Health Organization 2005). There are two general main purposes for the use of this technique: first, to identify key stakeholders and assess their interests and influences and second, to identify existing networks.

Professionals should keep their knowledge updated, since at present time it is easy of access to information so that they can't be excluded from dealing with imaging technique, such as Magnetic Resonance Imaging. But it is not enough to study and develop these skills. There are other skills that should be developed so that the MRI professional does not run the eventuality of being or becoming alienated of this technique. Therefore, after the identification of key decision makers involved, it will be interesting to understand and identify the skills that these decision makers hold (Maia and Moniz 2011).

5.4. Decision-Makers Competences

In order to start and apply a pre-test to a small group of DM, one Radiology Department was chosen. As seen previously in a Radiology Department we can find many different DM. To understand their competences, it is need to star by understanding their qualifications that are necessary and allows them to access their profession and to perform their tasks. This information was resumed in Table 3:

DM	Training Requirements
Clinician	Mandatory enrolment in College of Radiology, of the Medical Order.
Technical Assistant (office)	Trained with the level of education necessary for the proper performance of their duties. Computer training is considered essential in a user's perspective.
Operational Assistant	Trained with the level of education necessary for the proper performance of their duties.
Radiographer	Required official clearance for the profession, according to law. Degree in Radiology.
Radiologist (Physician)	Required registration in the College of Radiology, Order of Doctors.
Physicist Engineering	Required official capacity for the profession, according to law. Degree in Engineering Physics.

Table 3- Training requirements for the different decision-makers in a Radiology Department

In the attempt to understand the position of some DM regarding an self-evaluation of their competences, a methodology was developed, using as an example only one of the “knowledge” previously mentioned in chapter 1.3.1. (Competences for Decision-Making).
In order to collect some data, a pre-test was applied in a form of a questionnaire in a Radiology Department of a central public hospital.

5.4.1. The Pre-Test

To establish the opinion of respondents, a psychometric scale was chosen - the Likert scale. It is intended that, when responding to the questionnaire, respondents specify their level of agreement with the statement given. The scale went from 1 to 5, meaning:

- 1 - Few knowledge
- 2 - Some knowledge
- 3 - General knowledge
- 4 - Good knowledge
- 5 - Deep knowledge

In order to establish the component indicators, the information regarding the knowledge *per se* for each of one of the DM in the Radiology Department was gathered.

After some research, it was possible to find that, from all the four DM analysed only the Radiographer has his competences properly well defined. Taking into consideration the legislation, concerning the professional career of the Radiographer[11] and the Mission Report of the Grupo de Trabalho de Radiologia (Radiology Working Group) for the Implementation of the Bologna Process (Grupo de Trabalho de Radiologia 2004), the competences profile was outlined with the aim of framing the knowledge and skills in performing different tasks. Thereby, the information was added to establish a set of skills in an attempt to trace the profile for these professional skills, outlining to the following table, only considering the skills level of knowledge *per se* (Table 3):

[11] Decree-Law 564/99, 21 December

Competences by area	Knowledge in
Basic Sciences	Medical Sciences
	Physics Sciences
	Radiobiology
	Mathematics / Statistics
	Electronics
	Management
	Scientific Investigation
	Health Sciences / Patient Management
Scientific Area Sciences	Radiation Protection and Safety
	Quality Assurance
	Clinical Instrumentation
Specialty Sciences	Clinical Education
	Methods and Techniques in Radiology
Complementary disciplines	Behavioural Sciences
	Communication
	Information Systems

Table 4 - Radiographer's knowledge per se by competences areas
(Based on Mission Report of the Radiology Working Group for the Implementation of the Bologna Process, 2004)

For the other DM this characterization was not defined or the information was incomplete. For this reason, it was decided to adopt the Radiographer knowledge *per se* to the pre-test. To keep the analysis from becoming too complex and repetitive at this stage, a narrowing of the composite indicators number to use was made, having for background the transversal indicators for the five DM based on the Radiographers. As a result, seven composite indicators were established and identified.

These are the seven composite indicators that characterize the main indicator "knowledge *per se*". So that each one can be measured, a statement was established (see Table 5) so that the respondents could be able to classify them according to a self-evaluation using the pre-established Likert Scale.

ID	Composite Indicator	Statement
Q1	Medical Sciences	Knowledge about the structure, function and disease pattern of the human body. Includes knowledge of anatomy, physiology, pathology, biochemistry, etc...
Q2	Physical Sciences	General knowledge of radiation physics, required for implementing the various forms of imaging technologies.
Q3	Radiobiology and Radiation Protection	Knowledge for understanding the effects of radiation on the human body as well as radiological protection and safety.
Q4	Electronics and Clinical Instrumentation	Knowledge about the principles and operation of electronic devices and understanding of the equipment used in Radiology (MRI area) so that they can be used.
Q5	Management and Administration	Knowledge about different areas of management and administration techniques (knowledge in principles, techniques, and administrative tools, planning, organizing, leading, ensuring quality control, etc.).
Q6	Communication and Behavioural Sciences	Knowledge that allow interacting / acting effectively in various situations as well as knowledge about the development and understanding of human behaviour at both sociological and psychological level.
Q7	Information Systems	Knowledge of the principles relating to the operation of computers and associated technology.

Table 5 - Composite indicator and statements for the Knowledge per se

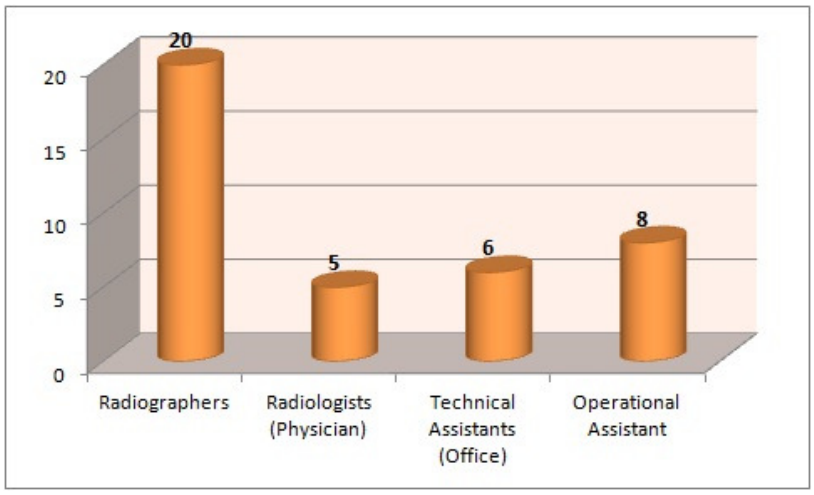
The questionnaire for the pre-test was then made.

5.4.2. The Analysis

The collected data was analysed, using the computer program EXCEL 2007 and the results represented in radar referential, with 7 vertices' each correspond to one of the seven composite indicators previously identified.

5.4.2.1. Characterization of the sample

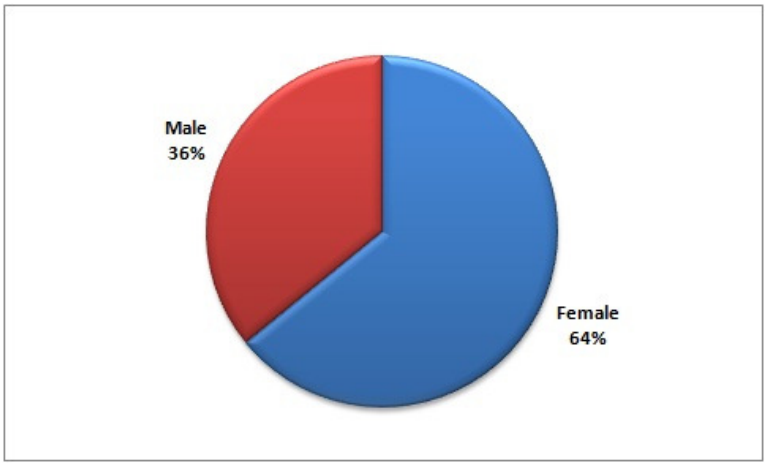
The questionnaire was applied to 39 main decision-makers with the following distribution:



Graphic 2 - Decision-makers distribution on the pre-test

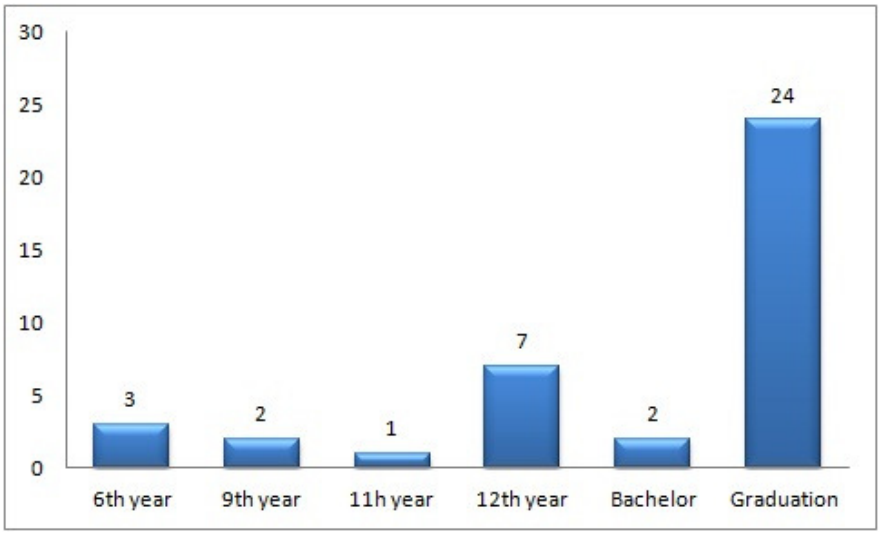
The majority of the DM, work with MRI equipment only in the public health sector (90 %) and only 5 % work simultaneously in the public and in the private sector. None of the interviewed only work with MRI in the private sector. Two of the interviewed didn't answer the question.

The average age of the interviewed was 37.7 years and they are mainly females (25, which represent 64%). Only 14 interviewed were male (see Graphic 3).



Graphic 3 - Sample's distribution according to gender

Regarding the academic qualifications (Graphic 4), 3 DM have the 6th scholar year (8 %), 2 have the 9th scholar year (5 %), only 1 have the 11th scholar year (3 %), 7 have the 12th scholar year (18 %), 2 accomplished a bachelor (5 %) and 24 DM (61 %) have a graduation. This imply that these 24 DM are the only one's who have an academic degree and since Radiographers and Radiologist are the only DM who must have an academic degree to fulfill their roles, this 61 % of interviewed correspond to them, with one exception: there is one Technical Assistant with a graduation.



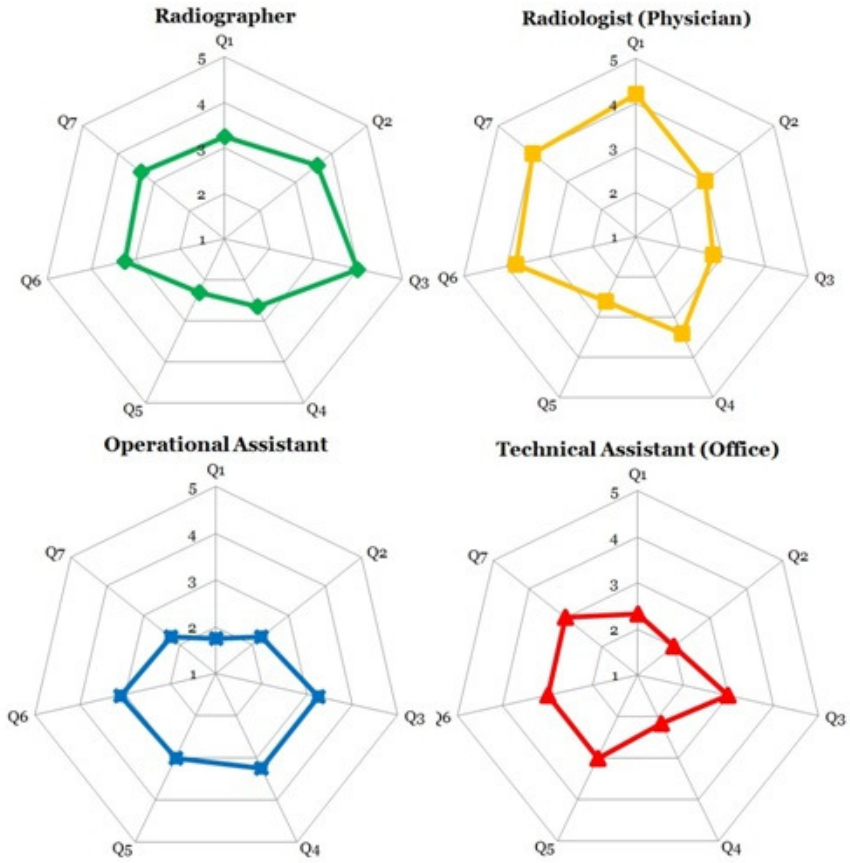
Graphic 4 - Sample's distribution according to academic qualification

In average, the 39 DM have been working in Radiology department for 12 years and present 4 years of working within MRI. Because this is a recent technology with so many specifications we can assist to this gap between the years of experience in Radiology and the years with MRI experience, not all professional can have access to work with these technology.

5.4.2.2. Characterization of the knowledge

In order to characterize the seven composite indicators, the data gathered from the answers given, were represented in radar graphic, where each of the radar branch correspond to a composite indicator.

Graphic 5 shows one radar graphic for each one of the DM.



Graphic 5 - Radar graphic for each decision-maker

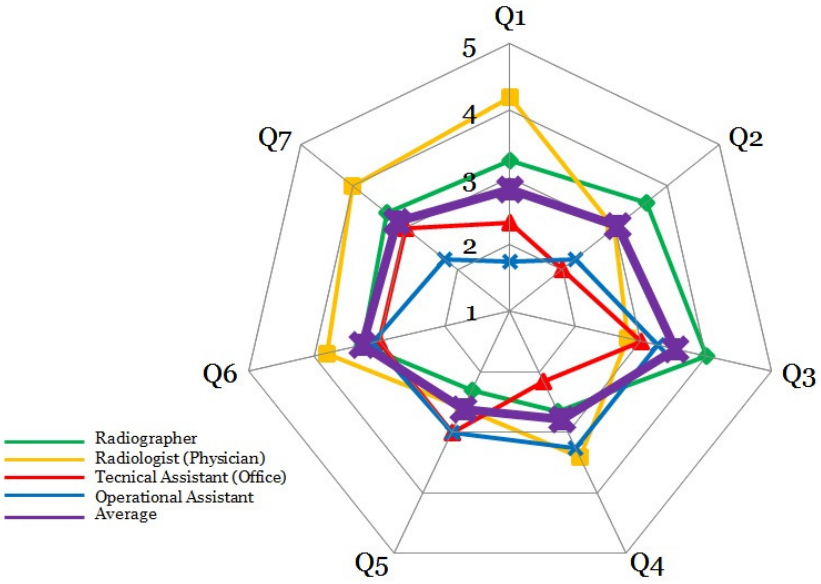
As we can see, some indicators appear closer to the referential centre and some are positioned far from it. When we look to the Radiographer's radar it is evident that there is uniformity on the results, since the radar is constant, without many pronounced vertices'. However Q3 (Radiobiology and Radiation Protection) shows a more prominent point, in congruence with the knowledge expected for this DM.

Regarding the Radiologist, Q1, Q6 and Q7 can be identified with the highest knowledge and the rest indicators stay more or less equal. Taking into account the background knowledge for these DM, it was expected that Q1 (Medical Sciences) appeared with the highest note - 5 (deep) - instead it appears with 4 (good).

The Operational Assistant radar also shows some uniform results. Q5 and Q6 have exactly the some score and Q3 and Q4 despite though slightly higher also present the some score as the previous one´s - general knowledge. Q7, 1 and 2 results are similar and classified as "some knowledge". In general results for this DM, and taking also into account his knowledge *per se* background it was unexpected the results for indicator Q3, 4 and 5 as for Q1 and 2.

For the Technical Assistant, Q3, 5, 6 and 7 present slightly the some result - 3 (general knowledge)) - and the some goes to Q1, 2 and 4 with the result 2 (some knowledge) which

indicates a homogenization regarding all knowledge. To have a more clear perspective of the global positioning, the combination of all four referential was made (Graphic 6).



Graphic 6 - Global Radar graphic for all decision-makers

By looking at this global representation we can see that it is in Q1, Q7, Q2 and Q3 that the DM positioned themselves away from each other. On the opposite, in Q5 and Q6 some points are overlapping. This fact indicates that for the first group of composite indicators, the knowledge of each group of DM tends to be differentiated. The opposite is applied for the second group, where the knowledge is more alike and it seems to exist some standardization in the answers given.

By taking into consideration the Likert scale previously defined, where 5 corresponds to a deep knowledge, the more dispersed the representation is, more specialized the knowledge tend to be, associated to the composite indicator. If we make an analysis taking this into consideration, Radiologist distance themselves from the other DM in Q1, Q7 and Q6 as this points are dispersed in relation to the others, which indicates that Radiologist present a more differentiated knowledge concerning Medical Sciences, Communication and Behavioural Sciences and Information Systems. On the other hand, Radiographers distinguish themselves when it concerns Physical Sciences and Radiobiology and Radiation Protection knowledge (composite indicator Q2 and Q3 respectively).

The other DM do not present a distinguished knowledge, in general terms. To make a more precise analysis, the average for each one of the composite indicator, according to the respondent, was calculated and then compared to a weighted average of all the collected data (Table 6).

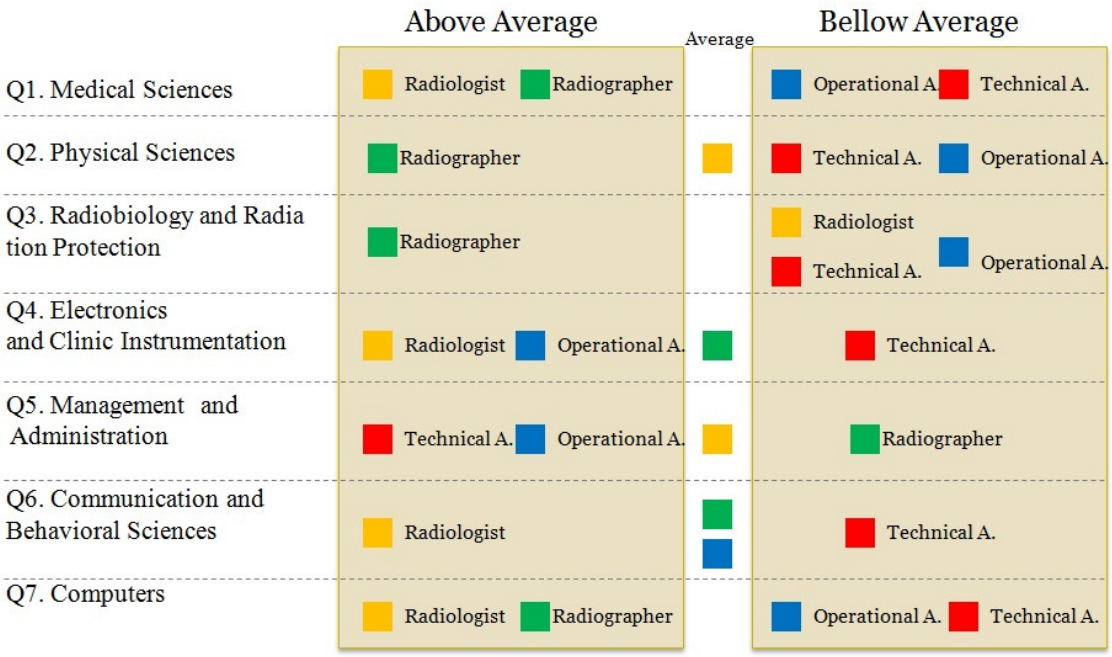


Table 6- Results of the pre-test according to the calculated average

From the analysis of Table 6, some of the results captured our attention:

- For Q1 and Q2 the results tend to mach the reality, has only the Radiologist and Radiographer have the necessary knowledge to stay above average, concerning medical and physical sciences knowledge.

- It is interesting to see that, for Q3 the Radiologist positioned themselvs below average. This kind of knowledge should be present for Radiologist, since they are also responsible (along with the Radiographer) to respect the ALARA principle (as low as reasonable achievable) concerning the radiation dose necessary to acquire quality images in the exam.

- Surprisingly the answers given regarding Q4 and Q5 positioned the Operational Assistant above the average. This specific knowledge is not given to this professional, since there aren't compulsory education to became an Operational Assistant.

- Management and Administration (Q5) are two major disciplines in the degree of Radiology, so it is surprising that the answers given by the Radiographers are positioned below the average. The some goes to Q4, since Electronics and Clinic Instrumentation are also specific disciplines of the course and for that Radiographers should positioned themselvs above the average.

- Regarding Q6 (Communication and Behavioural Science), although the Operational Assistant and the Radiographer possess expertise in this area, these two professionals should not be located on the same level compared with the average, in other words, there should be a distinction between these two professional position, since the Operational Assistant does not have prior theoretical knowledge, while the

Radiographer, has such knowledge since the same is provided in the university, while gaining his academic qualification.

6. Discussion

Some critics have already been made to this project. All of them were analysed and summarised so that they can be taken into account into the continuing project work.

The critics and suggestions were bulleted:

- Characterization of the National Portuguese Health System - The characterization of the National Portuguese Health System is needed in order to framework some issues and to have a better understanding regarding the public versus private health system and the access to some medical care (for example the MRI exams)

- Characterization of the MRI equipment status in Portugal - so that a clear characterization of the equipment can be develop, taking into account the geographical distributions of the equipment's, it's distribution in private and public sector, etc...

- Characterization of the chain value - the identification of the main stakeholders is need so that a chain value can be characterized. The relations between stakeholders have to be defined as well as the competences of each one in the process of decision making.

All the data gathered works like an incentive to the following work that has to be done.... In order to characterize the chain value, a decision-maker (or stakeholders) mapping has to be done. The data gathered concerning the MRI equipment have showed that there is still a gap between the private and public sector, in terms of MRI equipment, and that the western part of Portugal, is still the best equipped. These data need to be more precise and developed.

The questionnaire applied for the knowledge *per se* need to be applied to a national level and the other three types of knowledge need to be pre-tested and also applied to national level. These are only some of the task that is waiting to be worked upon.

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