

## Decision-making process in Radiology: the magnetic resonance example in the TA context <sup>22</sup>

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### Abstract

In order to understand the decision-making process in a Radiology Department, taking the Magnetic Resonance Equipment as an example, this paper reports a project to be followed. It is a guideline for future work development regarding Technology Assessment in Radiology. The Theoretical Framework is divided in three big issues. The first is "Technology Assessment". Starting with the definition of some important concepts, the history and development of Technology Assessment will be addressed. The aim of this issue is to give a general main idea concerning TA contextualization. Doing a transposition of this subject to health area, it is also important to understand the particularities of Health Technology Assessment, second issue. Portuguese framework on this subject will also be addressed. As so, the Portuguese National Health System is characterized and the decision-making stakeholders identified, as well as the competences for the decision-making process in general. The third issue is Decision-Making and its aim is to give a general elucidation on decision-making matters. 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

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decision making key stakeholders and a survey will be applied to map their skills and competences in the process, where a pre-test was already applied. The results of this pre-test are presented

**Key-Words:** Health Technology Assessment, Radiology, Magnetic Resonance Imaging, Decision-Making, Stakeholders, Competences.

**JEL codes:** I18, M15, O33

## 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).

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 3 Tesla (T).

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<sup>23</sup>.

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".<sup>24</sup> 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)

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

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<sup>23</sup> See Tallinn University of Technology - Technology Governance website at <http://hum.ttu.ee/tg/>

<sup>24</sup> See: [http://www.portaldasaude.pt/NR/rdonlyres/84FCFCE2-3C84-4ABE-8E5F-AD4DDB0B46F4/0/RelatorioGTRH\\_Nov2011.pdf](http://www.portaldasaude.pt/NR/rdonlyres/84FCFCE2-3C84-4ABE-8E5F-AD4DDB0B46F4/0/RelatorioGTRH_Nov2011.pdf)

Technology Assessment<sup>25</sup> 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.

# **Theoretical Framework**

## ***Technology Assessment***

In 1996 the Subcommittee on Science, Research and Development of the US House of Representatives 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' (TA) 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.

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<sup>26</sup>. 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

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<sup>25</sup> See: <http://www.htai.org/index.php?id=545>

<sup>26</sup> [http://www.fas.org/ota/technology\\_assessment\\_and\\_congress/houghton/](http://www.fas.org/ota/technology_assessment_and_congress/houghton/)

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).

### ***Health Technology Assessment***

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, 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.<sup>27</sup>

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).<sup>28</sup>

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).

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<sup>27</sup> From: <http://inahta.episerverhotell.net/Home/> (accessed on 25.01.2012)

<sup>28</sup> From: <http://www.htai.org/index.php?id=428> (accessed on 25.01.2012)

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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).

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 (Johnsson, 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<sup>29</sup>, 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<sup>30</sup> 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 beginning (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).

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

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<sup>29</sup> SBU is the Swedish acronym for the Swedish Council on Technology Assessment in Health Care. It was 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>)

<sup>30</sup> 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>).

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 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”<sup>31</sup>, 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

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<sup>31</sup> 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 práticas internacionais, teria as melhores condições para avaliar a inovação associando aos parâmetros de custo-efetividade o princípio de custo-opportunidade e tendo em conta a limitação de recursos e a necessidade de qualificar as escolhas.”



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 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.

Recently, Maia and Moniz when studying the competences for decision-making in Radiology, in a TA approach, concluded that HTA studies allow improving the clinical criteria for obtaining government information about the possible impact and on sequences of new technology, using a policy research that examines the short and long term consequences of applying particular technology. Thus, HTA contributes decisively to the consolidation of knowledge that contribute to improving the quality of health care, given the development and updating of standards, guidelines and health policies (Maia and Moniz 2011).

### ***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?

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- 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.

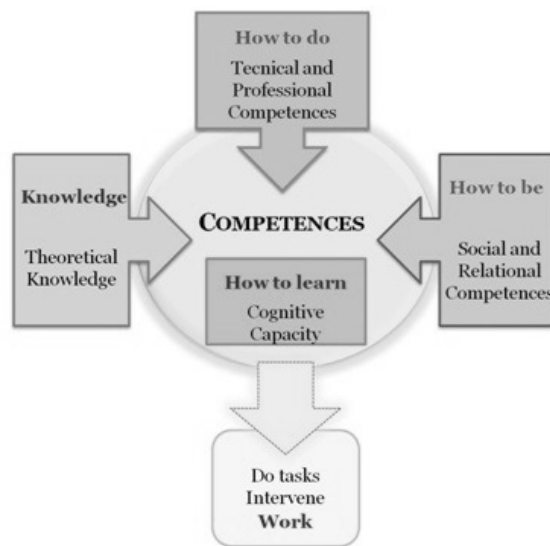
The "White Paper on Education and Training" also makes a remark, as a consequence of this new reality, some people go through situations of exclusion (European Commission 1995). For this not to happen, in a Radiology Department, in the Magnetic Resonance area (and beyond!) professionals must keep their 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 Organização Internacional do Trabalho - OIT (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 operationalised 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 1 - Schematization between the different "knowledge" and Skills**  
(Source: Maia 2011)

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.

### ***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.

### **Framework**

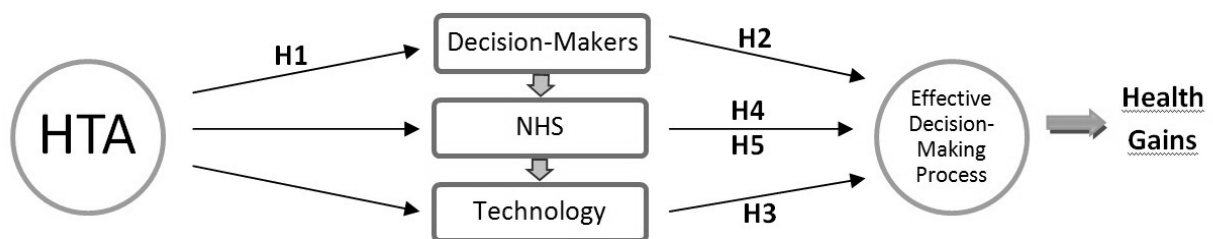
The methodology described is intended to answer the following questions:

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?

Here we purpose a framework of Technology Governance analysis 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:

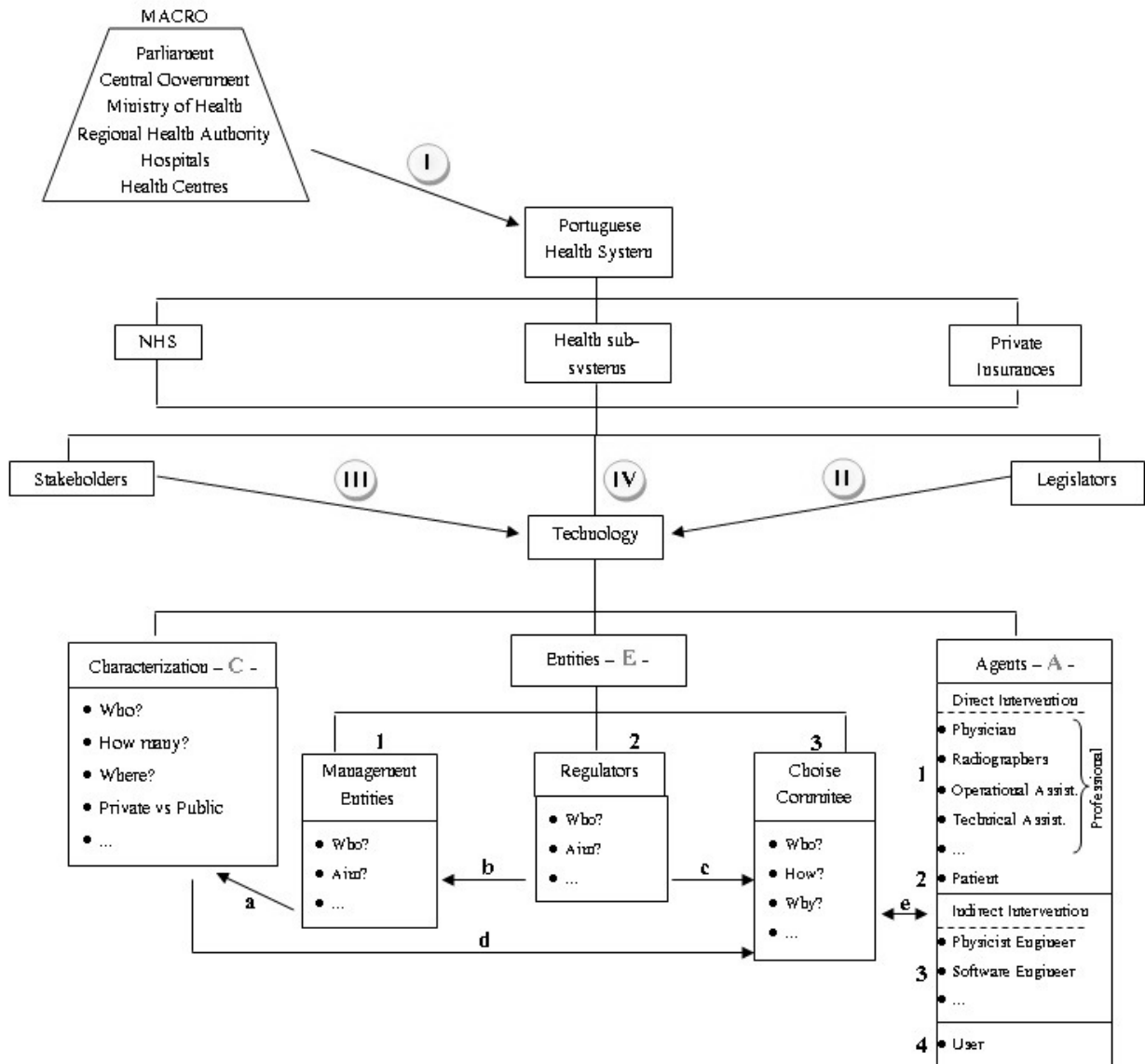
H1	The HTA in Radiology allows the identification of all decision makers (stakeholders) involved in decision making as well as their points of view. These are the decision makers who could be members of evaluation panels, as well as participants in future workshops on Radiology. The identification of 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 2 - Relationship between the hypothesis**

The conceptual framework is represented on Figure 6.



**Figure 3 - Conceptual Framework**

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

1. Q1 - A1, A2, A3  
E1, E2, E3, ...
  - o Q2 - those identified in Q1
  - o Q3 - a, b, c, d, e
  - o 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.

### ***MRI Equipments***

In order to study the MRI equipments 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) and 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 total representation.

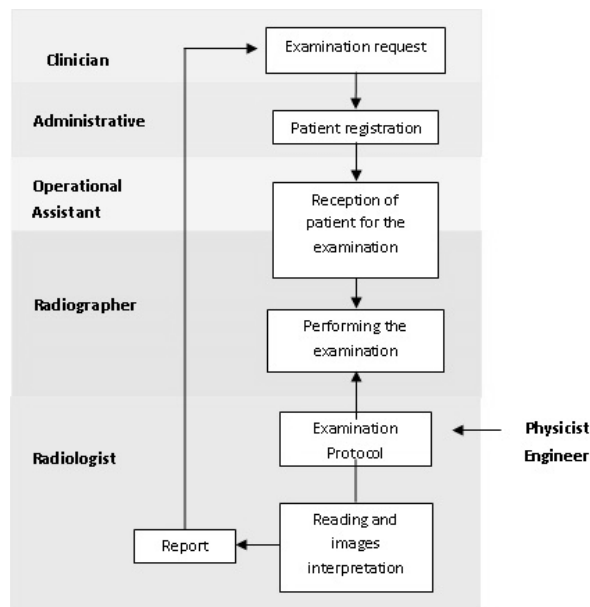
Firm	Sector					
	Public		Private		Total	
	nº	%	nº	%	nº	%
Phillips	9	8,57	27	25,71	36	61,71
Siemens	11	10,47	22	20,95	33	53,95
GE	--	--	--	--	30	28,57
Toshiba	0	0	6	5,71	6	5,71
Total	20	20	55	55	105	100

**Table 1 - MRI equipment distribution in Portugal, by firm and sector**

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







**Figure 5 - 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's identified in the example were the: Clinician, Administrative, Operational Assistant, Radiographer, Radiologist and 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).

## **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.

In the attempt to understand the position of some DM regarding a self-evaluation of their competences, a methodology was developed, using as an example only one of the "knowledge" previously mentioned in this article chapter on 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.

### ***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 and 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<sup>32</sup> 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.

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 indicators were established and identified.

These are the seven indicators that characterize the main composite 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	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 2 - Composite indicator and statements for the Knowledge *per se***

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<sup>32</sup> Decree-Law 564/99, 21 December

## ***The Pre-Test Analysis***

The collected data was analysed, using the computer program MS Excel 2007. The questionnaire was applied to 39 main decision-makers with the following distribution: 20 Radiographers, 5 Radiologist (physicians), 6 Technical Assistants (office) and 5 Operational Assistant. The majority of the DM, work with MRI equipment only in the public health sector (90 percent) and only 5 percent 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 percent). Only 14 interviewed were male. Regarding the academic qualifications, 3 DM have the 6th scholar year (8 percent), 2 have the 9th scholar year (5 percent), only 1 have the 11th scholar year (3 percent), 7 have the 12th scholar year (18 percent), 2 accomplished a bachelor (5 percent) and 24 DM (61 percent) have a graduation. This imply that these 24 DM are the only one who have an academic degree and since Radiographers and Radiologist are the only DM who must have an academic degree to fulfil their roles, this 61 percent of interviewed correspond to them, with one exception: there is one Technical Assistant with a graduation.

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.

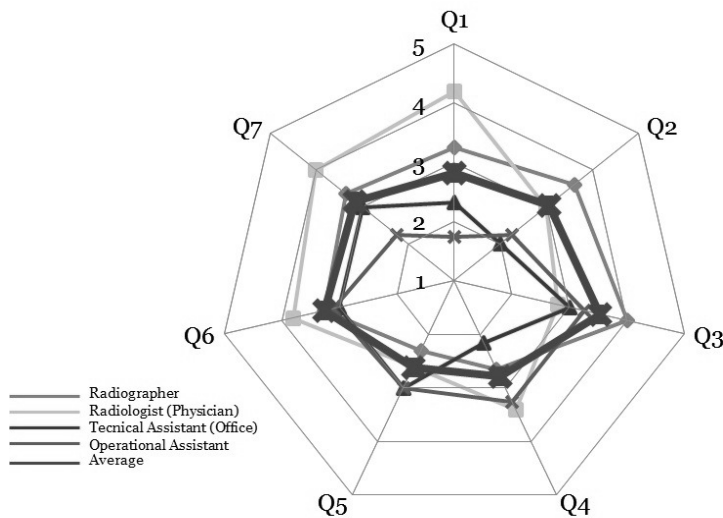
In order to characterize the seven composite indicators, the data gathered from the answers given, were represented in radar graphic, with 7 vertices' each that correspond to a composite indicator (Graphic 6). As we can see, some indicators appear closer to the referential centre and some are positioned 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.



**Graphic 1 - Global Radar graphic for all decision-makers**

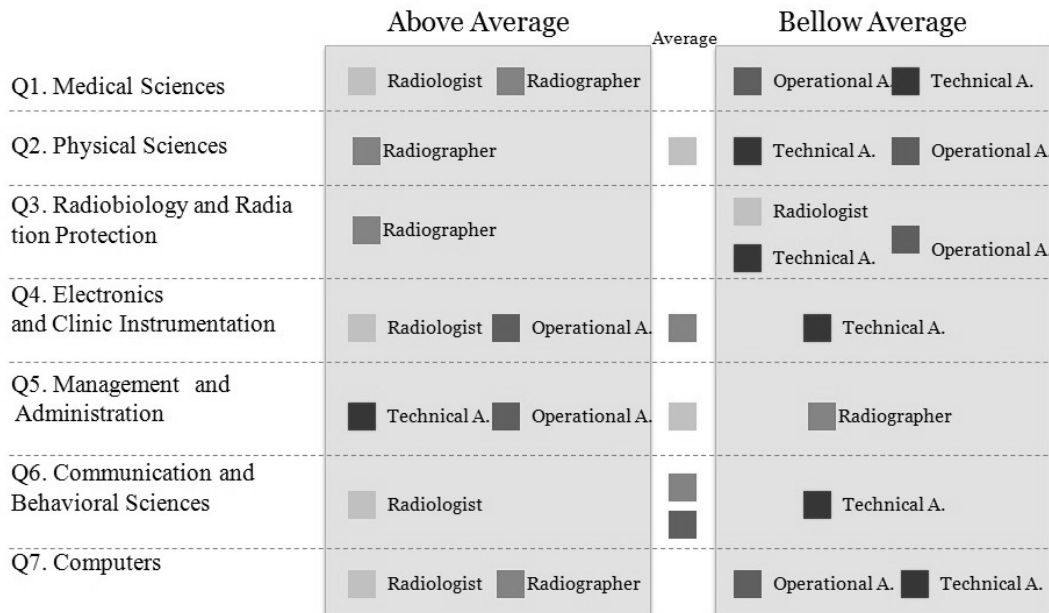
By looking at this global representation we can see that it is in Q1, Q7, Q2 and Q3 that the DM positioned themselves away from each other. On the opposite, in Q5 and Q6 some points are overlapping. This fact indicates that for the first group of composite indicators, the knowledge of each group of DM tends to be differentiated. The opposite is applied for the second group, where the knowledge is more alike and it seems to have 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 don't present a distinguished knowledge, in general terms. To

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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 3 - 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 match 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 themselves 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 is no compulsory education to become 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 same goes to Q4,

since Electronics and Clinic Instrumentation are also specific disciplines of the course and for that Radiographers should positioned themselves 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.

The main conclusions of this pre-test, corroborate those achieved by Maia and Moniz in their study (Maia and Moniz 2011). Decision-makers must be in possession of a set of knowledge and skills to enable them to accomplish their tasks. The training must however be adapted to the needs of each and conform to the task being performed. For this reason, also the TA should take particular account, the skills that are necessary for the different decision makers in a given organizational context.

## **Remarks**

One of the main challenges in health care is to improve quality with less costs. Although this seems to have an impossible outcome, HTA studies can be very helpful in assisting good decision making to achieve such aim. For that, HTA should be considered as a multidisciplinary field of analysis and decision. It should consider the clinical, social, ethical as well as the economic and political implications of the development, introduction, dissemination, use and abandoned / replacement of a certain health technology.

HTA should be considered as a multidisciplinary field, with different scientific approaches. This enables also the possibility to identify and characterize all stakeholders involved in the decision-making process, since their knowledge will develop a critical role along the process.

Stakeholders competences, should be developed according to the task and role played by the stakeholder, in the decision making process. These competences are seen has skills, behaviours and attitudes that are fundamental to the achievement of desired results and therefore performance at work. This should not be forgotten in HTA. Since competences are operationalised at the level of "knowledge" it is important to characterize stakeholders' knowledge.

In Portugal, HTA is mainly being made in pharmaceutical area. Regarding medical devices there is no HTA studies being made, or even economic evaluations. For



this matter, it is important to give the first steps in this area, taking as an example the decision making process in Radiology, regarding medical devices, such as Magnetic Resonance Imaging equipment.

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