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Patient Participation in Hospital-Based HTA

Case: Adoption of Hemics HandScan in the APHP

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Preface

With this thesis I complete my double master degree European Health Economics and Management. Although it has not always been easy and it has required quite some effort, it has enabled me to develop myself in directions I could have never foreseen. Before starting my bachelor studies, I was already convinced of my future interest in combining international cooperation and the healthcare sector. After obtaining my degree in *European Public Health* at Maastricht University, I figured that I strived to develop more practical and economic skills. And so, I decided to enroll in the international master program *European Health Economics and Management*, and it has been a wonderful experience. Those two years, both at Erasmus University Rotterdam and the University of Oslo, have prepared me to finally get my gained knowledge into practice soon. And yes, I am looking forward.

I would like to thank my supervisors, both in Rotterdam and Oslo, for their academic and warm, moral support during the process of my thesis. Thank you, Antoinette and Eline.

Also have I great thanks for everyone at Hemics, and especially for Petra and Wouter. During my internship there, they have supported me in writing my thesis while guiding me and offering insights into their work at Hemics alongside.

Last but definitely not least, I would like to use this opportunity to thank my dearest family and friends, who have always supported and believed in me through all these years. Especially on those moments when I got insecure, I have felt your moral support. Your motivational speeches has brought me further than I could ever have expected of myself.

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Abstract

Background**:** The patients' opinion and perspective are increasingly becoming important in the organization of healthcare. Consequently, many authors have argued in favor of more patient participation. Although there has been placed many efforts in arranging more opportunities for patient participation in all kinds of areas, there is not much known on the practice of patient participation in the technology evaluation and adoption processes by hospitals. Nevertheless, participation at this level has been recommended.

Aim: The aim of this research was to explore the role of the patient in the healthcare technology evaluation and uptake process of the *Assistance Publique – Hôpitaux de Paris* and more specifically, its hospital-based health technology assessment agency *Le Comité d'Évaluation des Technologies de Santé*. The foreseen evaluation and uptake process of a new imaging device for the monitoring of rheumatoid arthritis, the Hemics HandScan, was central and guiding in this study.

Methods: A qualitative research method was applied in this study. The data used was gathered from interviews, document analysis and a literature review. Interviews took place with several key stakeholders in the expected HandScan procurement process of the hospital, including member of the health technology assessment agency and several rheumatologists. Other interviews were with an expert on patient participation, rheumatoid arthritis patient or patient representatives on both national and European level. Document analysis refers to the hospitals specific documents, reports by the health technology assessment agency, and report/website analysis of the patient organization and European umbrella organization in rheumatism.

Results and conclusion: The evaluation of the HandScan includes both overlapping and distinctive values among the stakeholders. Irrespectively of the patients' distinctive opinion or perspective, in either of the two processes through which the HandScan could the adopted by the Paris hospital(s), patient participation seemed non-existent. According to this study, this could be explained by the differential attributed stakeholder position to the patient by all stakeholders. Those who currently have an influence on this evaluation and procurement process, do not consider to involve the patient. Those who would like to see the patient more involved in this process are the patient or patient representatives themselves. In other words, those who are involved in the evaluation and adoption of new healthcare technologies in the *Assistance Publique – Hôpitaux de Paris* and *Le Comité d'Évaluation des Technologies de Santé* attribute an external stakeholder position to the patient, except the patients or patient representative. This is also reflected in the desired rung on the patient participationladder. Consequently, in order to realize patient participation at the hospital-based healthcare technology evaluation and procurement process as recommended, first a consensus needs to be developed on the patients' internal stakeholder position.

List of Abbreviations

APHP	Assistance Publique – Hôpitaux de Paris
AdHopHTA	Adopting Hospital Based Health Technology Assessment – A European project.
AFLAR	Association Francaise de Lutte Anti-Rhumatismale ; *French Association of Anti-Rheumatic*
CEDIT	Le Comité d'Évaluation des Technologies de Santé; *The Committee fort the Evaluation of Health Technologies*
EULAR	The European League Against Rheumatism
HAS	Haute Autorité de Santé; *French National Authority for Health*
HB-HTA	Hospital-based Health Technology Assessment
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
PARE	People with Arthritis/Rheumatism in Europe; *Standing committee of EULAR*
RA	Rheumatoid Arthritis
SFR	Société Français de Rhumatologie; *French Society for Rheumatology*
T2T	Treat to Target

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1. Introduction

Within a society overloaded with the development of new technologies, innovations seem to be everywhere. Healthcare is in this matter not any different. Hospitals, generally the entrance for the adoption of novel technologies, feel that they must always innovate to enhance their efficiency and quality (Martelli, Lelong, Prognon, & Pineau, 2013). However, although there is always a tension to purchase a new medical technology, adoption of new treatments or medical devices is not necessarily always an improvement of the healthcare system. Therefore, purchasers of new technologies would like to evaluate these technologies upfront. This study addresses the very specific topic of patient participation in this evaluation process within a specific hospital context, and by using a specific healthcare technology case.

1.1. Rationale

During the last few decades there has been amplified effort in making healthcare more patient-centered. The patients' opinion and satisfaction has become progressively important. As a result, opportunities for patients to have a positive impact on the quality of public services and to democratize decision making have increased in many Western countries (van de Bovenkamp, Vollaard, Trappenburg, & Grit, 2013). Due to the growing emphasis on providing patient-focused healthcare, there is a tension to ensure patient involvement in the design of health services (Facey, et al., 2010). In other words, the trend to towards more patient participation in organizing healthcare (Van Veenendaal, 2004). Thus far, patients are quite represented in decision making on various subjects, such as research agenda setting, guideline development, governing policy making and quality projects in institutions (van de Bovenkamp, Trappenburg, & Grit, 2009). In line with this reasoning, several authors have stressed that including the patients' perspective in the evaluation of novel healthcare technologies is also important (Boote, Telforn, & Cooper, 2002) (Bridges & Jones, 2007) (Coulter, 2004) (Ong, 1996). As Facey and colleagues argued, if we have moved to an era where we want the patient to work in an active partnership with their health professionals, rather than as the passive recipients of healthcare, it is reasonable that they must also take part in those healthcare technology evaluations by healthcare institutes (Facey, et al., 2010). Thus, patient influence is not only important when it comes down to making choices among the treatments his treating physician suggests, or in other words,

shared-decision making on the individual level. No, the question arises if or whether patients should have the ability to decide which services (diagnosis, treatments and monitoring) his physician is able to offer in the first place. Or better said, whether they should be attributed power on the collective level.

Currently, the hospital needs to operate under financial restrictions and is therefore forced to set priorities and make decisions regarding the availability of treatment options. Underlying feature of the decision making process is the formulation of available alternatives that will (partially) meet the specific needs, and the choice based on the extent the alternatives meet the goals and objective of the decision maker (HBSP, 2006). A tool to make those decisions is health technology assessment (hereafter HTA) which is described as the multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implication in the development, diffusion and use of health technology (Drummond, et al., 2008). However, this type of systematic assessment is often solely applied on national level in order to facilitate national health policy choices and reimbursement decisions. While according to Saaid, Stewart, England and Parmar (2011) hospitals as providers of healthcare are the main buyers of equipment, they provide the bulk of costly, high-technology services and thus are the most important users (Saaid, Stewart, England, & Parmar, 2011). Although HTA is developed initially to facilitate decision making on national level, the number of hospital-based HTA activities has shown to grow globally (Gagnon, 2014). This could be explained as hospitals generally face the same issues as the national or regional decision makers in deciding whether to purchase a new technology for a clinical department (Martelli, et al., 2015).

The International Network of Agencies for Health Technology Assessment (hereafter INAHTA) has acknowledged a trend of patient participation in HTA activities (Hailey, et al., 2011). However, although there are studies promoting and encouraging greater patient involvement in HTA, only a few could be found which discuss the participation of patients in HTA at a local or hospital level (Facey, et al., 2010) (Gagnon, et al., 2009) (Gagnon, et al., 2012). The AdHopHTA Handbook, which is the result of a research project on hospital-based technology assessments funded by the European Commission, provides information and insights on the decision making process and managing of technology adoption by hospital (Sampietro-Colom, et al., 2015). Accordingly, this Handbook stresses the importance of

patient involvement as well, yet they lack the information and tools on how to arrange this appropriately. Therefore, the aim of this study to gain more knowledge on the desirability and feasibility of more patient involvement in hospital-based HTA (hereafter HB-HTA).

1.2. Case

The expected evaluation of a new imaging device for Rheumatoid Arthritis (hereafter RA), the Hemics HandScan, in comparison with current care, will be the case study aimed at addressing this topic. The innovative imaging device detects inflammations in the hand objectively, and is aimed to replace the currently used and subjective DAS28 for the monitoring of RA. Based on general HTA literature, adoption of this novel technology by hospitals would most likely be based on the technological, medical, organizational and economic reasons, while the (perhaps non-medical) impact or change on patients is often not considered. Nevertheless, the question is whether including the patient's opinion in this HTA process of a specific medical device could or would make a difference in the final decision. More background information on the Hemics HandScan and drivers for a differential patient perspective can be read in following chapter.

1.3. Setting

This study dives into the context of a specific hospital, namely the *Assistance Publique – Hopitaux de Paris* (hereafter APHP) in Paris, France. The Paris region accounts for approximately twelve million inhabitants and the region has both public and private hospitals. The APHP is a public health establishment with seven connected regional universities (Assistance Publique - Hôpitaux de Paris, 2016). The APHP was established in 1849 and is unique as it is the largest hospital center in the European Region. The APHP has three missions, namely: healthcare, research and teaching (Barna, 2013). It is a large organization covering 39 hospitals (twelve hospitals groups), treating more than seven million patients with an annual budget of around 7.2 billion euro, which mainly originates from national solidarity (Assistance Publique - Hôpitaux de Paris, 2016). All APHP hospitals combined feature 126 medical centers, 720 wards, more than 20000 beds and more than 300 operating theaters (Assistance Publique - Hôpitaux de Paris, 2016).

The APHP has its own hospital-based HTA agency, *le Comité d'évaluation et de diffusion des innovations technologiques* (hereafter CEDIT). The Committee for Evaluation and Diffusion of Innovative Technologies was established in 1982 and is considered the first HB-HTA agency in Europe. CEDIT provides advice on technological innovation matters aimed at supporting strategic procurement decisions. Comparable to other HTA units internationally, CEDIT is responsible for these recommendations to the Director General of the APHP. CEDIT consists of a committee (twenty medical experts and five representatives of the administrative departments) and scientific secretariat (a multidisciplinary HTA team) (Barna, 2013). Members of the CEDIT are appointed by the Director General of APHP.

1.4. Objective and relevance

The primary goal of this study is to assess the level of patient participation when the APHP considers to purchase an innovative technology such as the HandScan. Central is the evaluation process at CEDIT, but also the general purchase process of the APHP. The perceived patient position by CEDIT and the APHP, the patients' stakeholder character and position on the participationladder are guiding in this study.

From an academic perspective this study finds its relevance in knowledge contribution. Not only the current situation at APHP is described, but also the perceived opportunities and challenges faced when involving patients are revealed. Much has been written on whether patient participation should be done at national level, and to a much smaller extent hospital level, but little is known whether or how this is done in practice. The information gained by this study would therefore add to the existing literature on hospital-based HTA and patient participation. More practically speaking, this information could also be useful for those stakeholders involved. For hospital-based decision makers, as involving patients in the evaluation process could potentially affect the final procurement decisions. For HB-HTA committees, as this study may provide them insights on opportunities or consequences of involving patients in their processes. For patients and patient organizations, as gaining insights on their role and the potential of their participation may strengthen their position. And last, for the industry, as information on the technology uptake processes by hospitals may facilitate them in the diffusion of their products.

1.5. Research question

The research question on which this study is based is formulated as follows:

> *What position do patients have in the hospital-based HTA agency – the Committee for Evaluation and Diffusion of Innovative Technologies (CEDIT), of the Assistance Publique – Hopitaux de Paris (APHP) and would a change in level of participation be desired?*

Sub questions of this research question are the following:

- *How does the technology evaluation and uptake process look like for APHP/CEDIT?*
- *What role do patients play in this process?*
    - *Are they considered an internal or external stakeholder?*
    - *What is their position on the participationladder as described by Arnstein (1969)?*
- *How can current patient position and desired patient position be assembled?*

1.6. Outline thesis

This introduction will be followed by a chapter offering more information to the reader on the case study, the Hemics HandScan. The third chapter provides the theoretical concepts underlying in this study. Here, the state-of-the-art regarding HB-HTA and patient participation are presented and described according to the recent literature. In addition, several relevant theories supporting the importance of patient participation are also presented here. The fourth chapter provides insights to the research methods applied in this study. Most striking results of the obtained data will be presented in the fifth chapter, followed by a discussion, conclusion and recommendations in the last chapter.

2. Case study Hemics® HandScan

Musculoskeletal disorders are the second most common cause of disability world-wide (Storhiem & Zwart, 2014). According to Buchbinder, Maher & Harris (2015), these conditions are even among the most burdensome (Buchbinder, Maher, & Harris, 2015). Musculoskeletal disorders cover a wide range of conditions such as RA, osteoarthritis, low back pain, neck pain, gout, low bone mineral density and several other conditions. RA is a chronic systematic inflammatory disease with peripheral synovitis as its main manifestation (Van Riel, 2014). The stage of illness is time- and patient-dependent and characterized by episodes of inflammation of the joints. RA is experienced by pain and stiffness, swelling and loss of function of the affected hands, feet or other parts of the patients' body. Additionally, RA causes several other and more general negative health effects (Van Riel, 2014). Unfortunately, episodic inflammations of the joint may lead to irreversible damage.

In order to prevent the burden of RA as much as possible, emphasis is placed on tight control. Tight control could be defined as frequent assessment of disease activity combined with an objective structured protocol to make treatment changes that maintain low disease activity or remission at an agreed target (Mahmood, Lesuis, Van Tuyl, van Riel, & Landewé, 2015). This method is internationally embraced since it allows to treat to target (hereafter T2T) and therefore leads to better outcomes, disease control, better functional status and higher productivity. Although there is much evidence for the therapeutic benefits of tight control, it appears to be difficult to place this into practice (Mahmood, Lesuis, Van Tuyl, van Riel, & Landewé, 2015).

The standard of care for monitoring of RA is among other things the DAS28. DAS28 stands for disease activity score in 28 joints. In order to calculate the patients' DAS28 score, a rheumatologist counts the number of swollen joints, counts the number of tender joints, takes blood samples to measure the erythrocyte sedimentation rate or C-reactive protein (biomarker for inflammation in whole body) and asks the patients to their perceived health state using a visual analogue score (VAS). Although this procedure is considered the standard of care in Europe, it is also considered suboptimal. The procedure is time-consuming, painful for patients (especially in case of an inflammatory episode) and rather subjective. The score is constructed on inconstant elements, such as pain experience and inconsequent clinical

examination, possibly resulting in inadequate inflammation scores. Moreover, DAS28 has not been validated for use in individual patients, has considerable test-retest variability and is also influenced by several factors unrelated to joint inflammation (Van Onna, et al., 2015). Other imaging techniques such as ultrasonography and MRI are more sensitive, but infeasible to have as standard of care. This is because these are too expensive for standard use and time-consuming, and are therefore rejected on economic and workflow grounds. Consequently, according to Van Onna et al (2015), there is an unmet need for objective, fast measurement of disease activity at low cost, and applicable during outpatient visits.

A new medical imaging device, the Hemics HandScan, promises to meet this need. The HandScan measures the level of light transmission of specific wavelengths quantitatively (Van Onna, et al., 2015). Inflammation of the joint leads to vascular changes, which causes a decrease in the transmission of light. The HandScan claims to be able to detect and measure the intensity of this change in an objective, safe and painless manner. Additionally, the measurement and analysis of results would cost only three minutes and does not necessarily need to be executed by the rheumatologist. Monitoring could therefore be done more often and medication could be adapted according to need. In other words, tight control is easier to achieve. The clinical improvements and workflow enhancements are the emphasized benefits of the HandScan. Nevertheless, adoption of this device would also directly impact the care of the patient. Beside pain reduction to zero during the synovitis examination - generally a good thing, the HandScan would also directly affect the relationship of the patient and their rheumatologist. The intention of the HandScan is that the patient, in absence of other indications, would usually only see their doctor in case an inflammation is found, which could be either more frequently or much less frequent than in their standard care. However, patients might have a highly valued relationship with their doctor and would perhaps prefer to continue seeing their physician on a regular basis, enabling them to discuss their daily-life issues, being in contact with them through physical examination and feel being *seen* by a professional human they trust, rather than by *another* new technology. Yet, this study is not to prove the patient has different values regarding the HandScan. This study just aims to highlight that they *could* have a different perspective, and as long their perspective is not asked, it could never be included in the evaluation of new technologies.

A brief overview of the potential added value as promoted by the manufacturer of the HandScan in comparison with the DAS28 can be found in Appendix 1. This brief overview has also been used several times to guide data collection.

3. Theoretical Framework

This chapter will briefly introduce several concepts and relevant theories. Initial focus will lay upon explaining concepts and trends in HB-HTA and patient participation. This is followed by a number of theories. The stakeholder theory could potentially explain why patient participation is important or why participation by patients should at least be considered when decisions are affecting a certain stakeholder group. The participationladder takes it a step further, by arguing that more participation is always better and uses a ladder to demonstrate the right direction to go with patient participation. The theory of asymmetric information reflects however a less optimistic side of patient participation, and reveals a potential cap.

3.1. HB-HTA

In repetition of what was already mention in the introduction, in order to provide answers on the expected value of potential new technologies, a HTA can be performed. HTA is a research-based and practice-oriented assessment of relevant available knowledge on both the direct and intended consequences of health technologies, and on their indirect and unintended consequences (HTAi, 2014). In their article, Drummond and colleagues (2008) described key principles for improved conduct of HTAs for resource allocation decisions. These key principles regard to the structure of HTA programs, methods of performing an HTA, processes for conduct, and the use of HTA in decision making (Drummond, et al., 2008). Some of these principle have strong references to patient involvement and the added value of patients opinion in conducting an HTA. For example, in Principle 1: '*The goal and scope of the HTA should be explicit and relevant to its use.* [Therefore,] *a detailed scoping document should be developed before initiation of the HTA process, with broad, multidisciplinary stakeholder involvement'* (Drummond, et al., 2008). Additionally, in this principle, emphasis is placed that using solely clinical outcomes may exclude important benefits and negative consequences of new technologies, such as patient preferences. Principle 2: '*HTA should be an unbiased and transparent exercise'* underscores the widespread interest in the process and results of HTA by multiple parties (including patients). A stronger recommendation for patient involvement is given in Principle 10: '*Those conducting HTAs should actively engage all stakeholder groups'*. To quote: '*HTA programs should actively engage all key stakeholders in all stages of the HTA process, as this is likely to result in technology assessments of higher*

quality that are more widely accepted and stand a greater chance of being implemented. Moreover, such an open process will enhance transparency and trust in the process as stakeholders develop a greater understanding of the criteria and standards used' (Drummond, et al., 2008). The full list of key principles can be found in Appendix 2. These examples of key principles show that it is recommended to involve patients in HTA practices.

Although they are still mainly conducted at national level, HTAs could also be performed specifically in the context of a hospital. This HB-HTA is focussed on implementing a new technology in that specific hospital. Therefore, different from national HTA, the evaluation is not only tailored to the context of the decision, but could also be performed more rapidly and timely. According to HTAi, a global scientific and professional HTA society, there exist four models for HB-HTA. These are the ambassador model, mini-HTA, internal committee and a HTA unit (see Table 1). They each differ in their level of organizational complexity or on their focus of action. For example, within the *ambassador model* the clinician plays a key role in the diffusion of the technology within the hospital, while in the *internal committee model* a multidisciplinary group or committee performs this evaluation. Whereas both ambassador model and internal committee model focus on the decisions in clinical practice, the HTA unit model and mini-HTA model focus on managerial decision making. In *mini-HTA* a single health professional participate in the assessment process through collecting evidence at organizational level in order to inform decision makers at an higher level (Ehlers, et al., 2006). The *HTA unit* is the most well-developed formal organizational structure within a hospital. Here, specialized personnel works on HTA at a full-time basis (Cicchetti, Marchetti, Dibidino, & Corio, 2007).

		Focus of Action	
		Clinical Practice	Managerial decision making
Organizational Complexity	High (Team-group-unit)	Internal Committee Model	HTA Unit Model
	Low (Individual)	Ambassador Model	Mini-HTA Model

Table 1: Models of HB HTA (Cicchetti, Marchetti, Dibidino, & Corio, 2007)

Although national HTA reports are often freely available, both clinicians and hospital managers feel that these reports do not meet their need for information. These national reports do not offer answers to their specific questions, cannot be applied to their daily practice or timing of the report is wrong (McGregor, 2006) (Kidholm, Ehlers, Korsbek, Kjaerby, & Beck, 2009) (Cicchetti, Marchetti, Dibidino, & Corio, 2007). Unfortunately for hospitals and the technology producing company, medical devices such as the HandScan will most likely initially not be assessed by a national HTA agency (de Bont, Severens, & Knies, 2016), and are therefore be more dependent on those hospital-based evaluations. Thus, through HB-HTA the hospital is able to prioritize among the innovative technologies and focus on those technologies which are most relevant for that hospital, allow for better investment and resource allocation decisions, and offers answers to hospitals' specific questions.

3.2. Patient participation

In believe that different players in healthcare hold different opinions, the last couple decades there has been put much effort in patient-centered care. To repeat, the patients' opinion and satisfaction has become progressively important, and increasing emphasis has been placed on providing patient-focused healthcare and ensuring patient involvement in the design of health services (Facey, et al., 2010) (Tritter & McCallum, 2006). No longer is it merely the physician, the healthcare institute or the national health authority that determines what is best for the patient, but a shift took place towards more shared-decision making.

A distinction that should be made in patient participation is that between participation at the individual level and that at the collective level. On the individual level mainly the importance is indeed on shared-decision making, requiring an active attitude of the patient in their *own* care. However, also on the collective level participation is expected, such as in decision making on governmental policy, involvement in medical research and guidelines development (van de Bovenkamp & Zuiderent-Jerak, 2013). With the focus on HB-HTA, participation at the collective level is the one under study in this research.

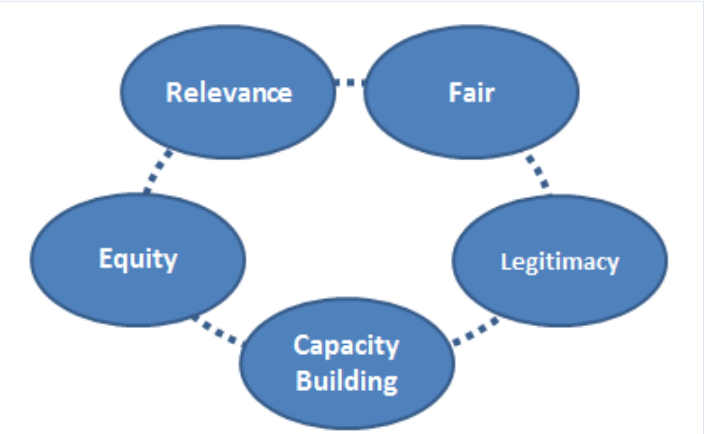

Figure 1: Values for patient involvement

There are several reasons why involving patients in the HB-HTA processes is expected to improve healthcare. HTAi, a scientific and professional society on HTA, summarized the importance of patient involvement on five main values, namely: Relevance, fair, equity, legitimacy and capacity building. First, relevance regards to the unique perspective of patients. According to Bridges and Jones, a major fear in HTA is that decisions in healthcare are not always based in the best interest of the patient (Bridges & Jones, 2007). Patients participation should lead to better quality decisions. Different from other stakeholders involved, patients have unique lived experience and knowledge, adding a new perspective when assessing a new health technology. However, their contribution will not only add knowledge and lived experience, but will also add a new perspective on what they consider valuable, and what not (Facey, et al., 2010). Perhaps it is not the HandScan the RA patient needs the hospital to invest in, but in psychological care. Perhaps it is not the objectivity of the device patients value the most, but the pain reduction during examination. Perhaps the patient prefers a regular physical check, to be in close contact with their doctor, rather than being scanned by a nurse. These are examples of how a patient could evaluate a technology on non-clinical grounds. Perhaps the patient fully agrees with the other stakeholders on the value of the new technology. The point here is, as long as these relevant preferences are not elicited, they cannot be taken into consideration, and care could never be truly patient-centered. Second, involving patients is fair as patients should have the same rights as any other stakeholder. Democratic participation of the patient is supposed to prevent procurement decisions made on other grounds. After all, most of these decisions made will affect the patient and therefore it could be argued that they should have a say in the process. Effective engagement is enabled once patients is given access to the HTA process. Third, patient involvement in HTA is considered equitable as it promotes involving all kinds of needs of patients within a healthcare system that aims to distribute all its resources fairly among all its patients. Fourth, patient involvement is legit as it involves those

who are affected most by the decision. Therefore it increases the accountability and credibility of the HTA process. Last, patient involvement is assumed to strengthen the capacity of patients and HTA organizations to work simultaneously while addressing barriers (HTAi, 2014). The values for patient involvement according HTAi are presented in Figure 1. Needless to say, through better patient-focused HTA processes, patient-centered care will be reinforced (Moreira, 2014).

As mentioned, patient participation at national level has received much attention and is greatly supported. In contrast, although there is support, patient participation in HB-HTA is limited or non-existent. Sampietro and collegues (authors of the renowned AdHopHTA Handbook), had set guiding principles for good practices of hospital-based health technology assessment in general. These guidelines have similarities to the more general HTA guidelines as presented by Drummond (2008). The Handbooks' guiding principle 3 is that hospital-based health technology process should involve all relevant stakeholders and be conducted in an unbiased an transparent manner ensuring the independence and proper communication of its results to hospital stakeholders. Interesting is that they specifically mention the patient as being an stakeholder, but also confirm that HB-HTA units lack patient involvement in the process (Sampietro-Colom, et al., 2016). The AdHopHTA Handbook stresses the importance of patient involvement, but lacks information on how to do so (Sampietro-Colom, et al., 2015). More information on the meaning of being a stakeholder according the theory can be read in following subchapter.

With regard to participation of patients in *national* HTA, there are several methods or practices known. Patient-based HTA could either be focused on the questions asked, or the HTA processes. Patient-based questions refer to focusing on the needs and problems faced by the patient, and addressing its needs and wishes. Technologies are evaluating incorporated with their perspective and preference. However, this could still be a very passive manner of involving the patient. Patient-based processes in HTA refers to the active and empowered role of the patient in the evaluation process. Either through communication, consultation or co-decision making. In active patient involvement, the patient is joining the discussion on the technology.

According to Hämeen-Antilla there are several criteria to judge successful public participation, namely; representativeness of the public or patient, an engaging participation process, availability and access to information that would promote understanding of the topic among all participants, and legitimacy of the process (Hämeen-Anttilla, et al., 2016). Unfortunately, although widely promoted, in HB-HTA there appears to be no emperical evidence of good or standard practices for patient involvement (Sampietro-Colom, et al., 2015). Therefore, there are no examples of succesful public participation to compare CEDIT with.

3.2.1. Participation of the RA patient

As the HandScan is the case study in this research and as not all patients or patient group are similar, the extent of participation and level of satisfaction of the RA patient is noteworthy. This gives us information on the practice of RA care and the potential desire of RA patients and patient organizations to change their level in participation. As most patient organizations, also the French patient organization for rheumatism, *Association Francaise de Lutte Anti-Rhumatismale* (hereafter AFLAR) strives for more influence in the organization of their healthcare (AFLAR, 2016). Also, the umbrella organization in rheumatic diseases in Europe, the European League Against Rheumatism (hereafter EULAR), has positioned the patient as one the three equal pillars; the researcher, the health professional and the patient (European League Against Rheumatism, 2016). These two examples reflect the desire for patient participation from the organization's point of view. Yet, although there is not much emperical evidence, there is one study by Kjeken and collegues (2006) on the satisfaction and involvement in healthcare from the patients' individual perspective. In their study, only a bit less than a quarter of RA patients considered their involvement as 'much', while almost 30 per cent felt they were not involved at all. It may therefore not surprising that most patients agreed that there is a need for more involvement. Interestingly is that 30 per cent of the patients who reported no involvement also reported that there is also no desire for more involvement. (Kjeken, et al., 2006). So, based on these findings, it might be concluded that a substantial part of the individual RA patients would not feel anything for inclusion in HB-HTA. According this study performed by Kjeken et al (2006) the most frequently reported need of RA patients are more time with healthcare provider, continuity, follow-up, and holistic care as the most important unmet need for rheumatology patients. Additionally and

in contrast with the no-needers, some patients stated their wishes for improved activity and participation, access to assistive devices and personal (Kjeken, et al., 2006). The findings by Kjeken et al (2006) indicate that *patients with more severe RA request more time to communicate their problems and needs, stable caregivers who follow their condition over time, and multidisciplinary care with cooperating team members* (Kjeken, et al., 2006). Thus, based on the results of this study, it seems that there is room for improvement in the way RA care is delivered. These findings in combination with the missions and aims of EULAR and AFLAR, show that in general the is a substantial desire towards patient participation, and thus potentially also in the evaluation of the HandScan.

3.3. Stakeholder theory, participationladder and theory of asymmetric information

Evidently, the main stakeholder in healthcare has always been the patient. As stated in the World Medical Association of Geneva 'the health of my patient will be my first consideration'. According to Angell, physicians (originally key decision makers in healthcare) have been guided historically by a normative ethic that provided order among the industry's stakeholders, placing the patient's health concerns above any other concern (Angell, 1993). However, in the development of healthcare processes and provisions it is not merely the patient, but to an increased extent other stakeholders with different incentives, such as payers and governing bodies, that play a role. Decisions in healthcare are no longer made purely based in the patient interest, but in those of many others. Although patient-centeredness –defined as respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patients values guide all clinical decisions- is not a new concept, it received renewed attention in last decade (Epstein, Fiscella, Lesser, & Stange, 2010).

3.3.1. Stakeholder theory

According to stakeholder theory, the primary goal of the hospital is to perform as efficiently as possible, and to generate as much value as possible for all stakeholders. However, existing literature offers several stakeholder classification definitions, which differ in acknowledging whether patients fall within one of them. For example, Nutt and Backhoff (1992) defined stakeholders as all parties that are affected by or will affect the organization's strategy (Nutt & Backoff, 1992). Obviously, they consider the patient as a stakeholder as the patient will

always be affected by hospitals' strategy. Less obvious is the patient stakeholder role as described by Eden and Ackerman as this assumes more power for the patient – stakeholders are either individuals or small groups with the power to respond to, negotiate with, and change the strategic future of the organization (Eden & Ackermann, 1998). According to Bryson a stakeholder is any person group or organization that can place a claim on the organization's attention, resources, or output, or is affected by that output (Bryson, 1995). Another definition is by Johnson and Scholes as those individuals or groups who depend on the organization to fulfil their own goals and on whom, in turn, the organization depends (Johnson & Scholes, 2002). As can be read, each author has a different interpretation and a different level of inclusion. For the purpose of this study and based on the motivations for patient participation in HB-HTA, it is chosen to use the definition of Nutt and Backhoff as a starting point.

In an optimal situation all stakeholders have the same interests (Freeman, Wicks, Parmar, & De Colle, 2010). However, the stakeholders in the procurement decision of the APHP have most-likely both overlapping *and* distinctive values. It is important to understand that the perceived value of a new technology like the HandScan may differ among the hospitals' stakeholders. In the context of the HandScan and the APHP, examples of stakeholders are APHP-staff such as rheumatologists, hospital board(s) or hospital managers, the hospital investing committee(s), the HandScan manufacturer Hemics or the umbrella organization for rheumatic illnesses EULAR. Or more related to the patient, the patients themselves, EULARs' standing committee of all European rheumatic patient organizations (PARE), or the specific French patient organization AFLAR. Among these stakeholders, values in the evaluation of technologies may range for instance from clinical aspects, financial impact, workflow improvement, ethical constraints, hospital strategies or to patient-doctor relationship. Since healthcare allocation decisions are value-driven, it is essential that the highest and most transparent stakeholder involvement is achieved (Rappagliosi, 2010). More general, the stakeholder theory is a theory on organizational management and business ethics that addresses morals and values. The theory focus on the optimization of a business or organization, and could either be used to describe all stakeholders stakeholder analysis or use as a managerial tool to understand to impact of those stakeholders involved. Basically, the theory looks at the relationship of an organization to others. It focuses on these

relationships and how these have an impact on the business of an organization. The specific relationship under study here is that of the patient with the APHP in the context of a technology uptake. As Freeman, the main contributor to the stakeholder theory, has argued: in order to keep an organization healthy, the relationships with all stakeholders should remain healthy and fruitful (Freeman, Wicks, Parmar, & De Colle, 2010). Thus, in order to have the hospital working efficiently, patients as stakeholders to the hospital should be kept satisfied.

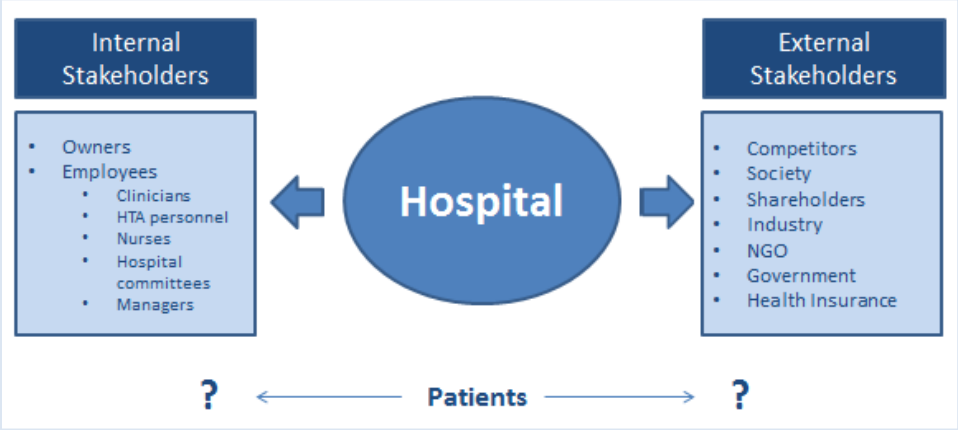

Figure 2: Stakeholder overview

In addition to the discrepancies in stakeholder classifications, stakeholders can also be divided into internal or external, as can be seen in Figure 2. Internal stakeholders tend to have direct power on the decisions made, whereas external mainly place influence on the policy rather than decide. Internal hospital stakeholders are those within an organization, for example, hospital boards, clinicians or other staff employees. External stakeholders are those outside an organization, such as the public, governments or other healthcare institutes. Specifically in HB-HTA, based on current practices, internal stakeholders are generally the medical staff, the HB-HTA agency/committee/unit, procurement office or financial department (Sampietro-Colom, et al., 2015). The external stakeholder in HB-HTA would be the technology manufacturer, hospital competitors, hospital shareholders or the general public. The patient, however, fulfills a more ambiguous role. On the one hand he is considered as a non-insider and therefore external, but on the other hand the patient is central in the whole healthcare system and could therefore be considered internal. In terms of power to the procurement decision, the question arises what the impact is of this rather undefined position of the patient.

3.3.2. Participationladder

Due to its guiding character for this study, the participationladder requires some extra attention. As Arnstein states, there is a critical difference between going through the empty ritual of participation and the real power needed to affect the outcome of the process (Arnstein, 1969). As she states, participation without redistribution of power is senseless. It allows those that have power to claim that all perspectives were included, but only make those decisions that are beneficial for themselves. Tritter and McCallum stated '*the sole measure of participation is power to make decisions, and seizing this control is the true aim of engagement*' (Tritter & McCallum, 2006). Originally, the participationladder was focussed on citizens in general but can be applied to patients easily. The simplified ladder consists of eight ladders, illustrating the often underestimated but nevertheless significant gradations of citizen participation (Arnstein, 1969). Being aware of these gradations enables to critically review current practices of patient participation in HTA and HB-HTA. The ladder can be seen in Figure 3. The first two rungs, manipulation and therapy, are non-participative. With regard to the case study, when the RA patient is placed in these rungs, it means that they do not have any decision power in the HandScan procurement decision of the APHP. The decision is made without the patient, and if the decision is reported afterwards, it would only be done to educate the patient or achieve support. The third rung is informing, which is the first step towards patient involvement. However, since the information flow is one-way is does not allow any feedback to the APHP or CEDIT. The RA patient would be informed that the HandScan will be purchased, but will not be in the position to express its approval, or nominate the HandScan or other technologies for evaluation in the first place. The fourth rung, consultation, allows eliciting the opinion of the RA patient, for example through surveys. Nevertheless, since there is no power alongside, this level of participation is considered as merely a ritual. The fifth rung allows patients to take part at the decision table, offering advice to those in charge directly. Here, the RA patient may share their perspective on the HandScan and discuss it with the decision makers. Again, since there is no

Figure 3: Patient participationladder

true power involved, this rang is another example of tokenism. The sixth rung is the primary rang which actually allows some kind of power. It would be redistributed from the original decision makers of the APHP, and be shared with the patient. The RA patient would be considered an equal partner, his or her input is just as valuable as that of the rest of the HB-HTA committee. The seventh rung takes it to the next level by allowing the patient to be in majority, they can take a decision. The last rung is patient control, where the patient deals with the complete decision. They plan, decide and manage the procurement decision (Arnstein, 1969). As a consequence, the other stakeholders have less to no power.

The level of patient participation is a matter on its own, and is not necessary related to their input. As mentioned, the stakeholders in the evaluation and uptake process of technologies have both overlapping *and* distinctive values when assessing a technology. Participation does not mean that the patient only makes decision based on their distinctive values, but that these values are at least given the opportunity to be taken into account.

3.3.3. Theory of asymmetric information

Both Freeman and Arnstein argue in favour of greater patient involvement. Freeman, as the patient is affected by the procurement decision of the hospital. Arnstein, as 'more participation is always better'. The reason why patients should be involved is partially based on the idea that patients have different information and different knowledge, and therefore add something to the discussion. Contrasting to the added value, some have argued that patients are not capable to make decisions that would be in their best interest *because* of the asymmetric information (Trappenburg, 2008). The stakeholder theory and participationladder are lacking arguments on the outcome benefits in case stakeholders are insufficiently capable to contribute. Should a patient, although affected by the decision made, join the HTA decision process without any medical knowledge on the technology under evaluation?

In a perfect market the information about a product or service delivered is equally available for both consumer and supplier. However, in healthcare this does not hold as the patient lacks the medical background, and is therefore not as qualified as his treating doctor to assess what is best for him or her medical-wise (Mwachofi & Al-Assaf, 2011). This asymmetrical information relationship between the doctor and the patient is therefore

regularly modelled within the agency theory. Different from other agency relationships is that the professional agency relationship includes at least part of the patients'/clients' interest in his own objectives (Evans, 1984). Here, the principal (the patient) delegates authority to the agent (the physician) to take action (Gafni, Charles, & Whelan, 1998). In a perfect doctor patient agency relationship, the doctor would offer all the information the patient need after which he or she would make a decision. Quoting Gafni and collegues, '*even though it might be the doctor who makes the treatment choice, it is the same choice that the patient would have made if she had the knowledge and information that her doctor has'* (Gafni, Charles, & Whelan, 1998). This principal-agent relationship could also be found in HTA processes. The health professional is expected to purchase those technologies that are at best interest for the patient. However, going to the other tail of asymmetric information, how can the health professional know what is best for or according to the patient?

This chapter brought together concepts in HB-HTA and patient participation with theories that either promote or question further development in the trend towards patient participation. Key principles in HTA and values for patient involvement convince us to realize patient participation. Motivation comes also from the underlying principles in the stakeholder theory and the participationladder. Yet, empirically there is not much evidence of patient participation at HB-HTA level. What causes this gap between what should be done and what is done, is still unclear. Could this potentially be explained by the asymmetrical information or agent-principal relationship between the health professional and patient? Or because of the undefined external-internal stakeholder position of the patient? Or are the many ranges and possibilities of participation resulting in uncertainty? These issues are addressed in the specific context of the APHP, with the use of the Hemics HandScan as a case study.

4. Research Methods

The methods used in a research study determines to a substantial level the quality of the results. This chapter will provide insights to the approach used to obtain an answer to the research question and related sub-questions.

4.1. Design

This study dives into the role of the RA patient in the expected evaluation and uptake process of the HandScan at f the APHP and its HB-HTA agency CEDIT. The study is descriptive and explorative by nature. Descriptive as it obtains and provides knowledge on technology adoption processes of the APHP. Explorative as it digs into a rather unknown field as there was no information public on the role of the patient within CEDIT practices. To repeat, the setting of this study is the APHP in Paris, France. By restricting to one setting specifically, information gathered on this topic can be more into detail and more precise. In order to answer the research question, this study will be making use of qualitative case study techniques (Yin, 1984) (Stake, 2000). A qualitative research method allows to perceive reality as a social construct rather than an objective measure (Babbie, 2003). A case study enables the researcher to explore and describe a phenomenon in depth by using a variety of data sources. By using several sources, it is ensured that the issue is not perceived through just one lens but multiple enabling to reveal and understand multiple facets of the issue (Baxter & Jack, 2008). Validity and accuracy was safeguarded through data triangulation. It was attempted by using observations, literature review, document analysis an interviews which would be contributing equally. However, due to difficulties in arranging settings for observing, the last three methods for collecting empirical data have been given the priority. Observational notes were solely made during communications with interviewees, for example, the willingness of contributing to this research, the facial or physical reactions to specific questions, and notes were made during the visits with the rheumatologist to observe what is going on at two rheumatology departments of the APHP.

4.2. Literature review

As part of understanding and answering the research question, first of all a review of the literature on patient participation within healthcare decision making was performed. Herewith, a current state-of-the-art could be obtained on HB-HTA and patient participation.

Search engines such as Google Scholar and PubMed were used to collect relevant literature. Search terms used involved inter alia: *APHP, CEDIT, patient involvement, patient participation, patient engagement, health technology assessment, hospital-based health technology assessment, national-regional-local HTA, procurement decisions, uptake processes, values in HTA, evaluation criteria, role patient organization, healthcare decision making, rheumatology, DAS28, stakeholder theory, agent-principal, shared decision making and patient-centeredness*. Mainly articles were used that included several search terms simultaneously. Additional articles were also found in reference lists. The date of publication was considered important, especially for those topics that are trend-related, such as that of patient participation. However, some theory-related articles are older but were still considered valid as they are still used regularly by the scientific society and the content is still up-to-date. Although the setting of the research is France, merely English scientific articles were used.

4.3. Document and website review

In addition to the literature review, documents and reports have been very valuable in obtaining information. Documents and website of APHP revealed the structure of the organization and its missions. Specific CEDIT reports included technology assessments reports and thus allowed to gain knowledge on how these evaluations have been carried out in the past. The AdHopHTA project gave insights to the current practices in HB-HTA and provided recommendations on how it could be improved. Reports of EULAR provided insights to the goals, aims and recommendation for organizing rheumatology care in Europe. Website and reports of AFLAR revealed information on the mission and role of the French patient organization on rheumatology. The website of INAHTA and its covering documents also offered some values an key quality parameters of organizing HTA. Together with knowledge gathered from the literature review, the information found through this document collection formed the base for interview protocols. Some organization specific data were in French, and have therefore been translated into English.

4.4. Interviews

In addition to the literature review and document collection, semi-structured open-ended interviews were a key source of data. Characterized by its loose structure, the interviews

allowed to elicit information that could not have been collected otherwise. As this study aims to reveal patient participation in a very specific setting, the APHP and CEDIT, and with a specific patient group, RA patients, the interviewees were selected based upon their background.

In total 23 persons with different backgrounds were contacted. Contact was made via e-mail and by visiting offices of the French Society of Rheumatology, the CEDIT and the French patient organization AFLAR in Paris, France. In case of no response or loss of contact, these persons were also contacted via phone. Finally six persons agreed to an interview, which allowed this study to reveal perspective from the most relevant stakeholders. A description of the interviewees can be found in Table 1.

Reference in report	Organization	Position	Date Interview	Length
Expert patient participation	IBMG, Erasmus Univerity Rotterdam	Associate professor	April 22nd, 2016	23 min
Vice-President PARE	EULAR	PARE Vice president	April 26th, 2016	58 min
Member CEDIT	CEDIT	Biomedical engineer Member Scientific Secretariat CEDIT	May 3rd, 2016	34 min
Rheumatologist Cochin	APHP - Cochin Hospital, EULAR	Rheumatologist Head of department Director Research Center Professor Rheumatology	May 11th, 2016	68 min
Rheumatologist Saint Antoine	APHP - Saint Antoine	Rheumatologist President SFR	May 12th, 2016	40 min
President AFLAR	AFLAR	President Rheumatologist	May 13th, 2016 June 4th, 2016	26 min E-mail

Table 2: List of interviews

As the purpose of these interviews was to reveal their perspective on the level of patient participation in APHP decision making at technology procurement level, it was made sure that the interviews had a wide range of backgrounds. As different kind of information was needed from each of the interviews, there was no standardized protocol used. For each interview a new protocol was developed, with exception for the two rheumatologists. However, all protocols obviously covered multiple parallel topics, such as: *rheumatologist-patient relationship, the perceived position of the patient to the hospital, the level of involvement/participation, work of APHP-hospital, HB-HTA in general and at APHP/CEDIT, procurement/adaption of new technologies, decision making process, future of patient participation.*

4.5. Data analysis

The process of data analysis aimed at making sense and creating a deeper understanding of the data that is collected. All data (literature, reports, interviews and data from visits) is used and compared to each other. By this triangulation of data sources, interesting and conflicting information could be grasped, or hypothesis on the results could be confirmed.

Transcribing was immediately done after the interviews for two reasons. First, by transcribing immediately additional notes on the non-verbal reactions could be added to the responses. Second, this immediate analysis of the interview allowed the protocols for upcoming interviews to be adapted to the arisen new and interesting information given by one of the interviewees. The transcripts were read and re-read several times. Coding was done in three steps as described in the guidelines by Strauss and Corbin (1990), namely 1) open coding through breaking down, inspecting, comparing, conceptualizing, and classifying the interviews, 2) axial coding, by placing the initial open codes in the bigger picture by categorizing and mapping these codes so concepts are developed, 3) selective coding in which a theory is developed by linking and mapping the concepts. Hereafter, the outcome of this interview analysis is compared with the other data, such as literature and reports, in order to answer to develop answers to the research question.

4.6. Validity and reliability

During the process of this study, the validity and reliability was aimed to safeguard. The use of several data sources supposedly enhanced the validity of this research. Through using interviews, document analysis, literature and to a smaller extent also observations, the researcher was able to compare the collected data and check it for both similar and contrasting findings. Moreover, the subject of this thesis was highlighted by from different angels, such as the rheumatologists, CEDIT, patients and patient organization, and the European umbrella organization for rheumatism EULAR. To obtain perspectives from multiple stakeholders, it is believed that the results are more valid. Reliability or reproducibility of qualitative research is always a rather difficult matter, as reality is considered to be a social construct, and is able to develop over time (Mortelmans, 2009). Nevertheless, through openness on the methods used for gathering the data, and on the position of the researcher (intern at Hemics - manufacturer of the HandScan), facilitates in

indicating the reliability of this study by the reader. Although self-reflection in the process of this study was key, a certain level of subjectivity is unavoidable while during research. Yet, acknowledging this the impact of this noise was minimized. Through asking for confirmation or repetition of topics during the interviews, personal and subjective projection on the topic was limited.

4.7. Ethical considerations

It is up to the researcher to take all necessary steps to make sure that his or her research is performed in an ethical manner. In this case this means that all those who have been interviewed were asked for permission to record the interview and to use their input for this study.

5. Findings

Central to this study was the healthcare technology evaluation and procurement process within the APHP and its integrated HTA agency CEDIT. More specifically, the role of the patient in this process was a critical focus point. The Hemics HandScan as a new imaging device for the monitoring of RA patients has been very helpful in examining this issue. Mainly due to the fact that the several actors ánd patients may have a very different manner of perceiving and valuing this device. The HandScan would not only improve the health status of the RA patient, it would also change the relationship between the patient and its doctor.

The first two subchapters will provide knowledge and better understanding on the APHP and CEDIT, and on its dual technology procurement processes. This is followed by a subchapter on how different stakeholders perceive the HandScan, and how or whether the patient is participating in this procurement process. The final findings on stakeholder position, decision power and participationladder are grasped in the last subchapter.

5.1. APHP and CEDIT

Before one is able to gather the potential of patient participation in the procurement of the HandScan or similar technologies, one first needs to understand the hospital specific process of technology uptake in general. Globally there are many different types of hospitals with many different kind of technology assessment processes, each affecting the technology uptake process in its own manner. The APHP and CEDIT being the setting of this research, this primary subchapter enlightens how the APHP functions, the role of CEDIT within the APHP, how CEDIT operates, and its impact on the final decision. This subchapter will conclude with a comparison between the hospital-based agency CEDIT and the national HTA agency *Haute Autorité de Santé* (hereafter HAS), and highlights the similarities and differences which might explain the presence or absence of patient participation at the technology assessment procedures.

5.1.1. APHP as a structure and the evaluation process of CEDIT

The APHP is a hospital structure or public health establishment promoting itself as one public hospital even though it consists of 39 separate sub-hospitals which are divided into 12

hospital groups. The division of the hospital groups has to do with one of the universities they are affiliated to. Due to its peculiar structure it is considered the largest hospital in Europe and one of the bigger hospitals in the world (APHP, 2016) (Assistance Publique - Hôpitaux de Paris, 2016). However, during this research it appeared that there is a division between the APHP acting as a *single-hospital*, and when it allows the APHP *sub-hospitals* to act on their own. An example, regarding some topics, such as in the procurement of drugs or something basic as paying the electricity bills, the APHP acts as one hospital (Rheumatologist Cochin, 2016). Simultaneously, regarding other occasions, sub-hospitals of the APHP are able to act by themselves, or even clinical departments act by themselves. Unfortunately, during this research it remained unrevealed which tasks exactly are at single-hospital level or at sub-hospital level. Yet, transparency on the distinction between the single-hospitals and sub-hospitals character of the APHP would allow us to understand which policies or decisions belong to the APHP culture, or which are sub-hospital specific. As a consequence, this would inform on which level patient participation should be organized. Either for each sub-hospital separately, or as a single patient participation policy for the entire APHP.

As pointed out, the APHP has their own HTA agency for the evaluation of new technologies. However, CEDIT is merely an agency that supports decision making, rather than making the procurement decision by itself (CEDIT scientific secretariat, 2016). Based on the HB-HTA models developed by Cicchetti (2007), CEDIT is could be described as an HTA unit: *A formal organizational structure based on specialized HTA personnel working on full time basis. This model represents the highest degree of structure for hospital HTA* (Cicchetti, Marchetti, Dibidino, & Corio, 2007). Requests for assessments mostly originate from practitioners of APHP (mainly physicians), decision makers of APHP or by self-request (innovations from horizon scanning). CEDIT analyzes, aggregates and makes a synthesis of all available data of the issue under evaluation. They use literature from primary and secondary sources, data from APHP and experts opinions to come to a recommendation regarding a technology. They will develop an HTA report addressing the technical, medical-clinical, economic and social acceptability aspects (Barna, 2013) (CEDIT scientific secretariat, 2016). The technical issues are first addressed in the assessment. This part will describe the new technology and includes information on the reliability and safety of the new device. Especially focus is laid on the competing and current practice. Additionally the user-friendliness and the steps

needed to install the new technology are addressed. In the second part the medical contribution and the quality of clinical evaluations is issued (Rodwin, 1992). Medical contribution regards to the patients' life expectancy, their quality of life, improvements in diagnostics, increased comfort for personnel, or the impact on future patients for diagnostic performance (Rodwin, 1992). Third part of the evaluation is supervising the potential ethical issues, however these are often not considered unless there is a direct motivation (for example for in antenatal technologies) (Rodwin, 1992) (CEDIT scientific secretariat, 2016). A study by Bodeau-Livinec and colleagues (2006) stressed the impact of the economic evaluation of a technology by CEDIT. However, in contradiction, this was not necessarily confirmed by CEDIT themselves (CEDIT scientific secretariat, 2016). As a matter of fact, according to the member of CEDIT, the criteria for evaluations cannot be weighed against each other, but should be perceived as a chain (CEDIT scientific secretariat, 2016). If one of the criteria cannot be met, no recommendation should be given, or merely under certain conditions. These restricted conditions could regard to the characteristics of the patient (for instance, the use of the HandScan would only be recommended for a specific group within RA), characteristics of the physicians or the specific heath institute (CEDIT Assistance Publique - Hôpitaux de Paris, 2016). Figure 4 visualizes this chain of CEDIT criteria. On their website, CEDIT publishes reports of their evaluations regularly. The reports of Aquapheresis (2015), SpotOn (2014) and Hemoglobin Monitoring (2015) are examples of medical devices that are evaluated for the use at the APHP hospitals. In confirmation, these reports of CEDIT indeed reveal that technologies are evaluated based on the technical, clinical, economic and organizational criteria and conclude with an advice. Noteworthy is that the patient's preference or perspective are not mentioned regarding the evaluation process, not during any interview on CEDIT, nor in the CEDIT evaluation reports.

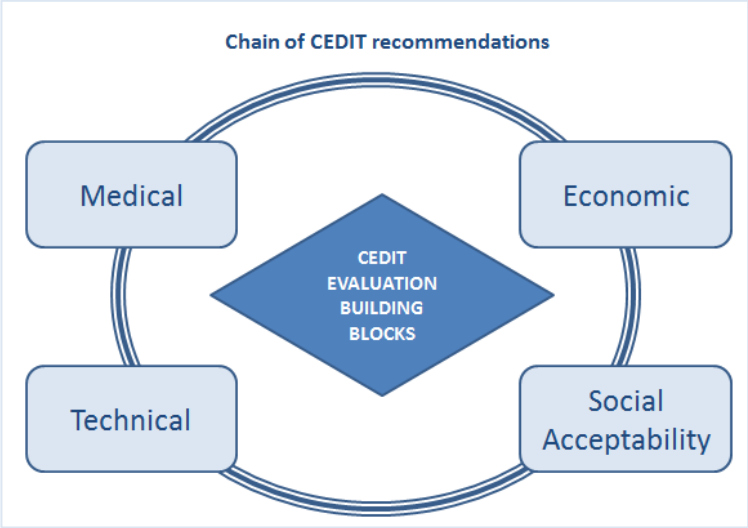

Figure 4: Criteria in CEDIT evaluations

5.1.1.1. Impact of CEDIT reports

The impact of CEDIT's work is relevant for patients to be aware of. In case impact would be small, it would not make much sense for them to participate. It would require needless effort in organizing participation if there is only small effect in final decision making. On the contrary, when impact is large, patients might have a very motivated attitude towards participation. Likewise, this impact of CEDIT is also relevant for the manufacturer of the HandScan. If impact is high, it means that focusing on a positive recommendation by CEDIT is something considerable to strive for.

There have been several studies showing the strong impact of HTA recommendations given by HTA agencies (Hailey, Corabian, Harstall, & Schneider, 2000) (Jacob & Battista, 1993) and therefore in general, their work is considered important. Nevertheless, according to the member of CEDIT, the exact impact remains difficult to grasp, especially in cases when HTA reports are not binding with respect to the procurement decision making. This CEDIT member believes this is a general problem of HTA agencies, and therefore not only of CEDIT (CEDIT scientific secretariat, 2016). Nowadays, CEDIT receives approximately twenty requests for evaluations annually, and is able to accept half of that. Historically CEDIT's recommendations were binding (Barna, 2013), but this has changed over the years. Despite its non-binding character, CEDIT sees their recommendations often followed, yet they find it difficult to grasps to which extent the procurement decision is based on a CEDIT recommendation or by other means. To quote the member of CEDIT: '*Well, there is a recommendation, but a recommendation is not binding. I mean, in itself* [...] *I think we are followed quite frequently, but this is a very difficult issue. Fundamentally, if the decision maker does it as we proposed. One, you have to define what that means, how close it has to be. Ok? And then, if they do, how do you know that it is because of our recommendation. I mean, there may be other reasons to in conformity of wat we say. So, it is very difficult to give an answer'* (CEDIT scientific secretariat, 2016). According to CEDITs' member, there is no feedback to the committee or an official report on what grounds the final procurement decision is taken. Hence, it may be concluded that the true impact of CEDIT cannot be measured easily. Nonetheless, according to the rheumatologists and confirmed by literature, a positive CEDIT recommendation has proven to be convenient in the negotiations between doctors and their management. Especially in case hospital funding is difficult for a specific

innovative technology, or in case several departments are competing in the budget allocation (Rheumatologist Cochin, 2016) (Rheumatologist Saint-Antoine, 2016) (Bodeau-Livinec, Simon, Montagnier-Petrissans, Joël, & Féry-Lemonnier, 2006). In other words, a positive recommendation raises the credibility of a decision.

5.1.2. Difference national HTA agency HAS and HB-HTA CEDIT

As Bodeau-Livinec and colleagues have argued, (national) HTA bodies seem to have a strong impact (Bodeau-Livinec, Simon, Montagnier-Petrissans, Joël, & Féry-Lemonnier, 2006). Why would a hospital such as the APHP have their own HTA agency for evaluating technologies such as the HandScan? As could be read in the AdHopHTA Handbook, this could be explained as these bodies differ in the work they produce. Much has been written about local and national HTA, and to a smaller extent also regional HTA, but there does not seem to be a consensus on definitions. The Handbook showed the main differences in characteristics between national/regional agencies (considered to have the same procedures) and hospital agencies in terms of the assessment process, leadership/strategy and partnerships, resources and impacts. Questioning the context specific APHP and country specific differences, and the consequences for CEDIT compared to the national HTA agency HAS, the member of CEDIT outlined first the many similarities. According to him, many methods used for the evaluation of new technologies, such as the manner of information research, are apparently the same. The French national HTA body HAS evaluates technologies as CEDIT does with respect to the methods used. However, there are some crucial differences as well, which could be seen as differences in the operationalization of HTA.

First, the timeliness. Whereas on average it takes three months for a HB-HTA agency to perform an evaluation, it takes up to 12 to 24 months for a national HTA body (Sampietro-Colom, et al., 2015). This is confirmed by the member of CEDIT, according to him, they work with requests from within the APHP and are therefore able to perform an evaluation much quicker than an national body such as the HAS would be able to do. Nevertheless, according to Bodeau-Livinec and colleagues (2006), CEDIT is still criticized for speed in evaluation. The long-winded HTA procedures cannot keep up with the fast development of new technologies (Bodeau-Livinec, Simon, Montagnier-Petrissans, Joël, & Féry-Lemonnier, 2006). If there is no patient participation yet, it is expected that this would have an impact on the timeliness, as

it would potentially require even more time to organize. Second, as national bodies tend to focus on those problems or needs affecting the biggest number of patients, the technologies under evaluation may differ (CEDIT scientific secretariat, 2016) (Sampietro-Colom, et al., 2015). National HTA focus on impact on national budget and thus focus of the biggest patients groups or those with the biggest financial impact, whereas CEDIT will also consider technologies that will maybe only affect a small amount of patients, as the request comes from medical, paramedical or administrative staff from within the hospital (and a few via horizon-scanning by the committee itself). In addition, as demographics of patients vary across regions, HTA at local level is expected to respond more to local needs in comparison to national HTA. Third, CEDIT is able to work with specific APHP related data (CEDIT scientific secretariat, 2016). It has specific patient related information such the number of patients that will be treated, their demographics and epidemiological data. Furthermore, CEDIT is able to reveal what exactly needs to be done in this specific health institute for this technology to be implemented fruitfully, such as the number of nurses to be trained, and in which of the 39 sub-hospitals of the APHP this technology should be implemented. This can also be grasped from CEDITs' evaluation reports. Fourth, another large difference brought up is the availability of resources which are, according to the member of CEDIT, bigger for HAS than for them (CEDIT scientific secretariat, 2016).

With respect to structured patient participation, based on literature and website reports, the national HTA body HAS is influenced by the patient perspective in its technology appraisals, guidance and coverage decisions (Kreis, 2013) (Haute Autorité de Santé, 2016). Apparently, two out of the four HTA committees have each two members who represent consumers and patients with an equal status to the others. The committee for evaluation of medical devices and health technologies, relevant for the evaluation of the HandScan, however, do not have fixed patient members. Yet, patients representatives may still be heard, participate and give advice if deemed necessary (Kreis, 2013). Although there is some patient influence at national HTA level of France, this is not how it should be according to *more is better* mentality. Whether patient participation is organized at CEDIT level will be discussed later in this chapter.

Although they work autonomously, according to CEDIT, there is a strong tradition of cooperation between the hospital-based agency CEDIT and the national HTA agency HAS (CEDIT scientific secretariat, 2016). However, different from CEDIT, the task of HAS is mainly to perform assessments for reimbursement and pricing of technologies, either for pharmaceuticals, procedures or medical devices. Cooperation between CEDIT and HAS includes informal contacts, exchange of information and HTA reports, and formal contracts for sharing assessment duties (Sampietro-Colom, et al., 2015). Therefore, according to the member of CEDIT, CEDIT could also very well work as a subcontractor for HAS (CEDIT scientific secretariat, 2016). Consequently, as patient participation is valued at national level, in order to CEDIT to operate as a subcontractor, it is expected that the patient would also need to be involved at the HB-HTA level.

In conclusion, this subchapter offered information about APHP and its HB-HTA agency CEDIT. This facilitates in understanding how the HTA unit proceeds its evaluations before we can have a look at the bigger picture of the hospital adoption of technologies like the HandScan. As could be read, the HandScan is likely to be evaluated on its technical, medical, economic and social acceptability character by CEDIT, resulting in either a recommendation or not. Although the true impact could not be grasped in this study, according to the literature and based on interviews, these advices are expected to be followed. This means that effective patient participation at CEDIT would be meaningful to the final procurement decision. Moreover, this chapter has also provided insights to the hospital-based HTA character of CEDIT by comparing it with the national HTA body. Besides the many differences, there are also similarities to their methods used for evaluation. This could explain the strong cooperation between the two bodies. As could be read, HAS does involve patients to a certain extent, but whether CEDIT has patient influence will be discussed later. Using the dissemination of the HandScan as a case study, the following subchapter will first address the dual technology uptake processes of the APHP.

5.2. Uptake innovative devices by hospital

The APHP structure and CEDIT processes and impacts, as revealed in the previous subchapter, does not allow us to understand who enables the adoption of the HandScan. As new on the market, the manufacturers or producers would like to see the opportunities for

the uptake of the HandScan by hospitals explored. Based on the interviews with two rheumatologists and head of the rheumatology departments of different sub-hospitals of the APHP (Saint-Antoine hospital and Cochin hospital), the uptake process for the APHP hospitals appears to be two-sided. On the one hand there seems to be a formal route of adopting new technologies via an officially structured path. On the other hand, there seems to be a rather informal route. This subchapter will provide insights on these two constructed processes and elicits the dual meaning of CEDIT.

5.2.1. Official process

Based on interviews, APHP/CEDIT websites and reports, an official procedure for the uptake of new technologies was constructed, which is reflected in Figure 5. It all starts with a new technology available on the market, one that claims to improve the organization of healthcare. The steps below reflect on how the HandScan will be adopted in case it would follow this official process.

1. The APHP hospital staff, in this case for example a rheumatologist, becomes aware of the new imaging technology the HandScan, and sees potential in the added value of this technology. Sometimes the added value of a new technology is so obvious (very effective and at low cost) that there is no need for an in depth added value assessment by an HTA agency. Yet sometimes the APHP staff is unsure about its added value, or the new technology is that expensive that they really need to be sure. For the purpose of this study, this is assumed to be the case for the HandScan. Then an official recommendation would be in place for the APHP to validate a procurement decision.
2. After concluding that an official evaluation is in place due to insecurity or high budget impact, either the administrative staff, medical staff or paramedical staff will hand in a request at CEDIT for the evaluation of the HandScan.
3. CEDIT performs an evaluation based on the criteria as described in previous sub-chapter. It will gather the technical information available on the HandScan, the financial impact of adopting, the required organizational changes such as training of staff or space/environment changes, or ethical-legal considerations. After an evaluation based on those criteria, CEDIT gives either no recommendation, a

recommendation or a recommendation under certain circumstances for the purchase of the HandScan.

4. CEDIT reports back to those who made the initial requests, send an report to those who are on a distribution e-mail list and might be interested in the outcome as well, and will publish a report on the HandScan on their website.
5. Hereafter, a final procurement decision can be made by either: the administrative, medical or paramedical staff; a subcommittee for investment and works; or the Director General of the APHP. Who eventually take the final decision is mostly depending on financial impact of purchasing this technology on the hospital. Decisions on technologies with a lower budget impact are often made at the department level. However, technologies like the HandScan, with a substantial or high budget impact would need to be approved by the subcommittee investment and works, and cannot be purchased without permission. In case of truly expensive technologies with a massive budget impact, an approval of the Director General is required. The economic threshold for these different levels of decision making were not obtained during this study. This is unfortunate as this would reveal at what level the final purchase decision for the HandScan is expected be made. (Rheumatologist Saint-Antoine, 2016) (CEDIT scientific secretariat, 2016) (CEDIT Assistance Publique - Hôpitaux de Paris, 2016).

Yet, it is expected that a costly technology as the HandScan, medical departments of an APHP sub-hospital cannot make purchase decisions themselves. Therefore, a request would be needed to hand in at the subcommittee for investment and works. The committee will rank the requests for these kind of investments and gives purchasing permissions on an annual basis (Rheumatologist Saint-Antoine, 2016). A positive recommendation by CEDIT may add strength to the investment request. Once again, this process makes clear the merely supporting role of CEDIT. To quote CEDIT's member regarding the impact of the recommendation, '*it is really up to them what to do with the report*' (CEDIT scientific secretariat, 2016).

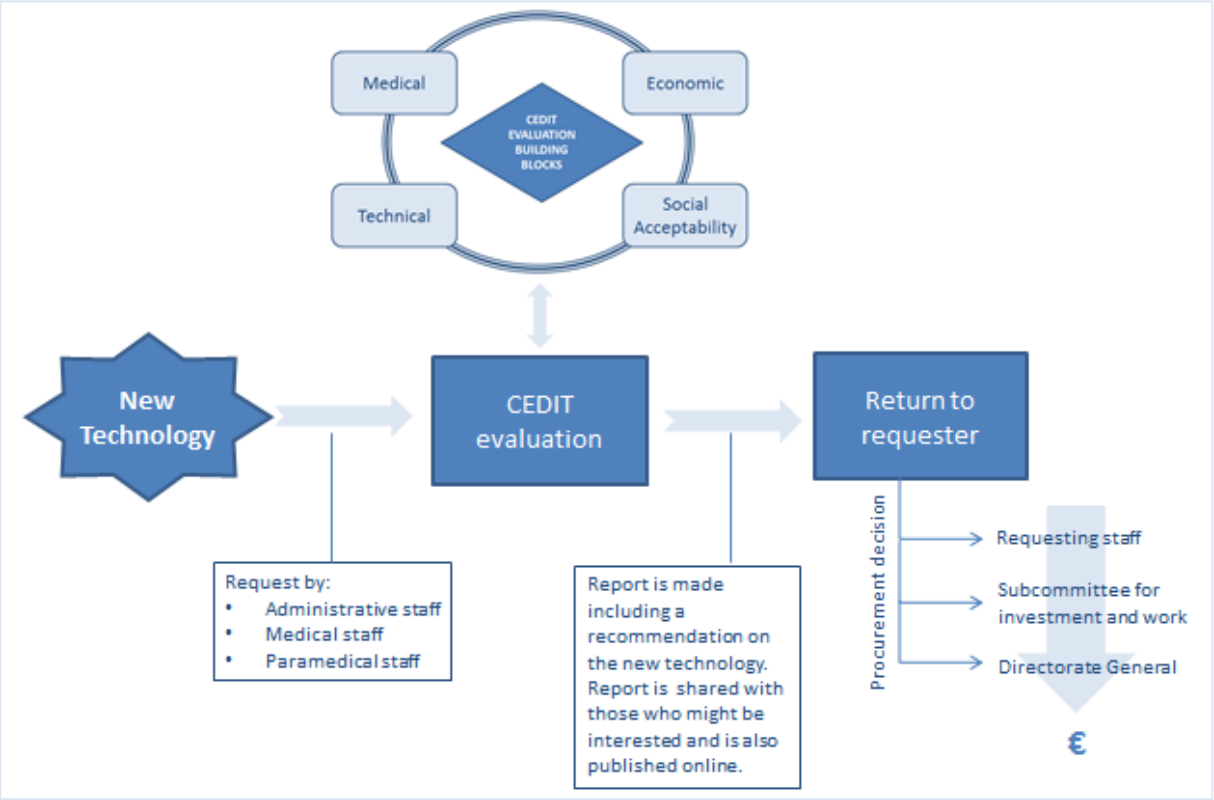

Figure 5: Formal technology uptake process at APHP

5.2.2. Non-official process

In dialogue with one of the rheumatologists, it became clear that not every medical technology uptake is via the formal route. This might be because, as one of the interviewees mentioned, the APHP is too big, too big to do something. Being so big makes it difficult to organize healthcare optimally (Rheumatologist Cochin, 2016). Requesting an evaluation at CEDIT will take too long. This rheumatologist pointed out that, in case he desires to have this device – the example given of the HandScan – he would make sure he would get it. To quote, '*Imagine, here we want to use this machine in my department. In the beginning it would be so complicated to have official authorization coming from the CEDT and APHP. The best way is to start, non-officially with this machine and then continue to apply to CEDIT after…. [..] .. Do not start from scratch, from the top we do nothing*' (Rheumatologist Cochin, 2016). Unfortunately, during the timeframe of this study it was unable to have this unofficial process confirmed or further explained by other staff from the APHP or CEDIT. However, the manufacturers of the HandScan did not seem to be surprised. This process seemed to confirm their experiences with other rheumatologists (non-APHP). Especially in case the rheumatologist is renowned for their work in the field, they will have the power and tools to

do so (Hemics, 2016). If the rheumatologists desire to have a HandScan, they will make it happen and do not necessarily need a recommendation from an HB-HTA body.

Hence, based on the research during this study, there are assumingly two pathways for the HandScan to be adopted by the APHP, either through an official route with a prominent role for the HB-HTA unit, or through an unofficial route with less leading role of CEDIT recommendations. With regard to patient participation in the uptake of novel technologies this is relevant, as it reveals who is currently in charge of the decision or where patient participation should take place. With respect to the official path, should this at the level of the requester so that those questions and processes in HTA are patient-based? Or at CEDIT, where technologies are evaluated? Or at final procurement decision level such as at the clinical department level or investment committee? The following subchapter addresses the current level of patient participation along the uptake process of the HandScan, and reveals the prospects of increased patient participation in the future based on these findings.

5.3. Patient participation along the expected HandScan uptake process

Although these processes provide insights on how the APHP or rheumatology departments proceed in the uptake of new technologies such as the HandScan, this has not provided answers to the level of patient participation in this process. Considering patient participation through both questions and processes in HTA, this subchapter address both CEDIT and the rheumatology department/subcommittee for investment and work, and reveals the reasons why it is organized as it is, based on this study. As the HandScan is the case study, this subchapter starts with an elaboration on the values and criteria in evaluating this technology by relevant stakeholders as revealed from the interviews. The subchapter finishes with applying these findings to the yet undefined internal/external stakeholder position of the patient, and with the desired level on the patient participationladder according to the stakeholders in the HandScan uptake process.

5.3.1. Different perspectives, different criteria for evaluating the HandScan

Confirmed by the theory that each stakeholder might have different opinion or expectations regarding the value of a new technology, the HandScan is also valued differently among the stakeholders. During the different stakeholder interviews, it became clear they indeed had

overlapping values, such as clinical improvements, but also different perspectives in evaluating a new technology were revealed. Based on the data gathered in this study, the most striking differences in perceiving the HandScan will be discussing in the following subheadings, according to their backgrounds.

1. Rheumatologist: The interviewed rheumatologists placed strong emphasis on the clinical added value of the HandScan. They ask questions regarding its objectivity, quantifiable test results, revealed clinical information by the HandScan and the possibility to better T2T. Also would they focus on the change in workflow, to what extent it would be easy to use and time-saving aspects. Pain or discomfort for the patient were mentioned, but were considered to be less important than the clinical improvements. No attention was given to the economic aspects (Rheumatologist Saint-Antoine, 2016) (Rheumatologist Cochin, 2016) (President AFLAR, 2016).
2. Patient/Patient representative: From the interview with the vice-president of PARE (EULAR) and RA patient himself, it became clear that he very much values the relationship with his personal doctor. He emphasized that this relationship is more than just clinical examination, and that he uses the consultations also to discuss his personal life and how it is affected by RA. When asked what is for him most important during consult, he replied: '*Unfortunately they* [doctors] *only have ten minutes, or fifteen the best. In that time there is no time for discussions, there is no time for doctor and patient to discuss the things that concerns the patients' life, especially if you are a person as I said in the beginning, where rheumatic muscular diseases affects all the aspects of life. The doctor should listen to these problems. Not only to the disease activity, not only to the blood tests, not only to the X-rays. But the doctor should also hear and listen and discuss other things, maybe for the patient is more important. Social life, family, sex and so on'* (PARE, 2016). Considering that the HandScan *will* have an impact on the relationship between patient and doctor, the patient will value the HandScan differently. Apart from this non-clinical perspective, PARE vice-president also pointed out that he values the painless and objective aspects of this HandScan. However, quality of life for the patient is key (PARE, 2016).
3. CEDIT: This matter has received attention earlier in this report. As mentioned, CEDIT uses technical, medical-clinical, economic and social acceptability aspects to evaluate. Based on the HTA reports CEDIT has published it can be assumed that the

HandScan will be recommended or not inter alia on its ability to measure synovitis objectively, its potential for workflow improvements at rheumatology departments, on the clinical advantages over the current practice such as the enhanced opportunity to T2T, the improved health outcomes of patients, its upfront purchasing costs, an economic evaluation (potential change in expensive biologic treatment use for RA patients), and the steps needed to take in order for the HandScan to be fully implemented (training of nurses, education of staff).

4. Subcommittee for investment and works: Regrettably, the researcher was unable to discuss this personally with members of such committee. However, an interview took place with head of a rheumatology department who has been in close contact with this committee. The criteria this investment committee seems to be using are or is rather straightforward. To quote the rheumatologist (after explaining the official process in the uptake of medical technologies by APHP): *'So, first the CEDIT. Then there is a recommendation for added value. Then in each department there is a demand for I would like this equipment. You will have to convince the committee* [subcommittee for investment and work], *to convince that this will add money for your department, not value for the patient. Nobody cares for that. The patient is not important. The money is important. If you are asking for a new device, a new equipment, then you will have to show in parallel what that will add in terms of money for the hospital. And that's it.'* (Rheumatologist Saint-Antoine, 2016). Here he reveals immediately the level of and attitude towards patient participation at this level. Thus, as he explicitly mentions that there is first a CEDIT recommendation, it can be concluded that a clinical added value is already proven. After that, based on this information, only the financial impact seems to be relevant.

As can be read, each stakeholder in this process focuses on different aspects when evaluating a new technology such as the HandScan. It can be argued that on many aspects there is definitely an overlap in criteria and value. The HandScan generates both shared values, and potentially opposite values among the stakeholders. Using the prescription of Freeman (2010), it is up to the APHP to generate as much value as possible for *all* stakeholders. Thus, as there are also opposite values, trade-offs have to be made. The main question is whether the perspective of the patient is even considered, and whether a trade-

off is even made. The following subchapters, finally, discusses the actual participation of the patient.

5.3.2. Patient participation at CEDIT

Immediately, after doing some research and speaking to those involved, it became clear there is no room for the patients' perspective in the evaluations of CEDIT. Neither the HTA-questions, nor the HTA-processes are patient based. For example, no requests from the patient or patients representative are available or considered, patients are not involved in prioritizing among the requests (which technologies would be most valued for evaluations by patients) and neither involved in the evaluation of those technologies under study (the patient perspective does not take part in the criteria-chain, or is present during the discussion) (CEDIT scientific secretariat, 2016). The interviewee, member of CEDIT, seemed even somewhat uncomfortable in admitting it by taking a long time to come to a rather simple conclusion and using unnecessary complicated sentences. As he argues, '*more practically speaking, we don't have any – how can I say? – patient influence initiative in terms of doing an HTA'* (CEDIT scientific secretariat, 2016). Moreover, there are some contradictions in his reasoning and wording such as '*I don't think there is any example of patient contribution to our HTA-work for the moment'* and '*So, there is very little patient contribution to our work, to summarize'* (CEDIT scientific secretariat, 2016) after very clearly stating there is obviously no patient participation, and in addition, also revealed a sense of 'of course not' and not even considered as an option. According to CEDIT, processes at this level are still very dominated by health professionals (CEDIT scientific secretariat, 2016).

5.3.2.1. Opinion and practice

As it is often with patient participation, also the member of CEDIT believes that fundamentally it is a good thing. However, he makes a distinction between patient centeredness at the individual level and on the community level. A distinction that was also found in the opinion of the clinicians. The member of CEDIT states that it is even *obvious* that the patient has a lot of influence when it considers his personal care. According to him patients are, or at least should be, central in organizing healthcare. Yet, as he continues, '*whether patients should decide [..] on how the hospital should be organized inside, is another issue'.* Using the example of robot surgery, he clearly demonstrates his opinion

regarding the influence of patients in an investment decision. Concerning the risks and benefits of using this technique he argues that '*the patient can be informed, they can make a decision* [on whether or not to use this technique for their own care], *but they cannot really decide whether or not a hospital is going to invest in a robotic surgery or not'.* The use of 'we cannot' or 'they cannot' which has not only been used here by him, but multiple times during the interview on patient participation at CEDIT, reveals a sense of impracticality or infeasibility, and left the interviewer with an impression of asking a question that has never been addressed before. Addressing the future of patient participation at CEDIT, its member cannot deny that it could possibly be developed. However, this has more to do with the unavoidable trend then an intrinsic desire or believe that it should be done (CEDIT scientific secretariat, 2016).

5.3.2.2. Responsibility, feasibility and power

Based on the information obtained in this study, it can be assumed that the reasons why there is no room for patient participation are grounded in the lack of responsibility, lack of feasibility and the aspiration to conserve power. When addressing the potential reasons why there isn't any patient involvement in the evaluation processes of CEDIT, its member seemed to distance himself or CEDIT from the responsibility to do so. He mentions how CEDIT merely mirrors the requests of the APHP. To quote: '*We mainly respond to what the various persons or parts of our organization asks us. The questions they ask us, they reflect the general policy of the APHP'* (CEDIT scientific secretariat, 2016). He points out that scientific secretariat only has four to five members. Compared to the entire APHP as an organization, CEDIT is so small and its member seems to argue here indirectly that they are too small to *also* organize patient participation. Not only does he distance himself from patient-based HTA processes, but also from patient-based HTA-questions. According to the member of CEDIT, as it are others that suggest technologies, CEDIT is not responsible for which technologies are under evaluation. However, in contrast to no responsibility, it is still up to the scientific secretary of CEDIT (he does not mention 'we', potentially to distance himself from that decision) to decide which requests among all requests will be answered.

Regarding the involvement of patients in the evaluations process there is no strong opposition towards it, however, it is just not done. Stated by CEDIT, the cases evaluated did have a need to involve patients (CEDIT scientific secretariat, 2016). This is interesting as this

potentially reveals that he does not see any added value in it, neither as in better decision making, nor in democratic reasoning. In addition, it reasonable to argue that he just does not believe in its feasibility. As pointed out before, patient participation at this level is regularly mentioned in combination with 'cannot' and a sense of 'of course not'. As the member of CEDIT points out, whereas at the individual level of care the patient is still central, on the community or policy level this is just unfeasible. Accordingly, CEDIT continues by arguing that patient participation equals equal partnership, equal power and equal knowledge (CEDIT scientific secretariat, 2016). Especially with regard to knowledge, he believes the patient would require the same in order to add something to the evaluation. To quote: *´It's quite obvious that the patient and surgeon don't know- have the same knowledge about surgery. It is very difficult for the patient to have the same knowledge'* (CEDIT scientific secretariat, 2016). Here he addresses the one-direction of asymmetrical information, the patient would need the same knowledge as the decision maker in order to co-decide or co-evaluate. In addition to questioning the value of patient participation at CEDIT, he mentions several impracticalities. He questions the ability to reveal an autonomous patient opinion. Should one patient representative be accountable for the availability of a certain technology? Should that be from the patient organization? Should a technology-specific patient group be represented? With regard to the capability and professional differences among the patient organizations, is this than fair? He argues that it will be difficult to indicate the general patients will (CEDIT scientific secretariat, 2016).

To conclude, although there are general recommendations by AdHopHTA to involve patients in HB-HTA, based on this study patient participation is non-existent at CEDIT. This is not because patient participation is rejected in general, but because CEDIT doubts its feasibility to arrange, not consider it is up to the HB-HTA unit to involve patients, or in general does not see a point in patient participation at this level. These results indicate how CEDIT perceives the patient and the potential role it should play in the evaluation and uptake of new technologies.

5.3.3. Patient participation at rheumatology and investment committee

With respect to the official technology uptake process it is either the medical, paramedical or administrative staff of the APHP that hands in the requests at CEDIT. Since there is no patient participation at CEDIT, and considering the unofficial path for the uptake of

technologies, perhaps the rheumatologists or investment committee involve patients. Either before handing in a request at CEDIT or before they make the procurement decision themselves according the unofficial uptake process. Interestingly, during this study it became clear that there is a contradiction in what the clinicians say and what they actually do regarding patient participation.

Addressing patient-centeredness and patient preference, the rheumatologists immediately responds with a certain needless-to-say or self-evidence. '*Nothing for the patient, without the patient'* responded one of the rheumatologist when asked how he perceives the patient, confirming the patient being an equal partner (Rheumatologist Cochin, 2016). He referred to EULAR, the umbrella organization for rheumatic muscle disorders, build on three equal pillars: the researchers, the health professionals ánd the patient. As he said, you need to involve the patient in any healthcare decision, you are not allowed to do anything without them (Rheumatologist Cochin, 2016). To quote: *'the most important actor is the patient'*. When asked another rheumatologist, he believed that including the patient preference should be a normality as well. To quote: '*Yes, we always take into account the patient preference'* and '*Yes, I really think that any decision* [in healthcare] *should be shared* [in consensus with the patient]*'.* Thus, the initial responses of the rheumatologists were somewhat direct and with a sense of 'of course, patient involvement is important'. Yet, in contrast with what they state, elaborating on how the patient or the patients' opinion is incorporated in the decisions made, the patient preference exposed itself as non-contributing. Perhaps because this is supposed to be the political correct answer, and it is incorrect to admit that you wouldn't use the patient perspective. To repeat from previous sub-chapter, the most important factor for a novel technology are, according the rheumatologist, the clinical impacts and as one of the rheumatologists revealed, only in case it would directly harm the patient, the patients' opinion is asked. To quote: '*So, if it is no pain for the patient, there is no problem'* (Rheumatologist Saint-Antoine, 2016). Thus, unless they the decision to make would harm the patient, there is no opinion asked, and there is no structural way of eliciting the patient preference. According to Cochin hospital rheumatologist, there are no patient representatives in the rheumatology departments to allow their opinion to play a role. However, neither is there a patient representative at the subcommittee for investment and work, where different clinical departments fight for a

positive procurement decision. To quote rheumatologist of Saint Antoine hospital: '*There is a commission at* [sub-hospital APHP] *where we discuss, there are representatives of the department and there is a discussion about how we have to rank the different equipment of the hospital. But the patient is never included into the discussion'* (Rheumatologist Saint-Antoine, 2016). Based on the interviews, it cannot be denied that both renowned rheumatologists seem to have never thought about the possibility of having the patient involved in the procurement process of medical devices such as the HandScan. For one it even took quite some time to even understand the relevance of the topic. Rheumatologist of Cochin hospital argued that in case a technology is good, it's good, and he wants to have it (Rheumatologist Cochin, 2016). However, he does not consider that his perception of good might differ of that with the patient.

Thus, based on the findings in this study, also at the rheumatology department and investment committee patient participation is not active. Similar as to the response of CEDIT, the rheumatologists were rather surprised by addressing the idea of patient participation in the procurement decision process of new technologies. Patient participation is for them initially related to treatment decisions on an individual level, shared decision making between patient and treating physician, and informed consent. With regards to the evaluation and purchase of devices as the HandScan, participation is not considered.

5.3.3.3. Power, assumed knowledge constraints, and feasibility

Although it was not ever considered yet, the interviewees were able to reveal some explanations why patient participation is not organized in the procurement of medical technologies. Potential reasoning is listed here below.

With respect to the HandScan, as long as the change of care from DAS28 to the HandScan would not harm the patient, the doctors don't see any reason to involve them. To quote: *'We consider that if there is no consequence for the patient in terms of pain or any other concern then the technical reason for which we need it is not in the hand of the patient. It is in our hand, as doctor'* (Rheumatologist Saint-Antoine, 2016). This last sentence, it is in our hand, seemed to reveal their perceived power. It should remain up to them, they should have the last word. The addressed question '*What if they say no?*' by rheumatologist of Saint

Antoine hospital, reveals some kind of impracticality, or perhaps even fear for the loss of decision power. Both rheumatologists placed emphasis on the differences in satisfaction of the patient and doctor. According to them, RA patients are satisfied when they do not experience pain or feel disabled, while the clinicians focus on synovitis and joint damage. Although in RA synovitis/joint damage and pain often go hand in hand, there could potentially be a situation where the patient is happy with their care (no pain), but the doctor isn't (synovitis), or the other way around (patient experiences pain, but no sign of synovitis). This is interesting, as it illustrates a challenge. This distinction in focus leads to difficulties in treatment adherence and a request for more care (Rheumatologist Saint-Antoine, 2016) (Rheumatologist Cochin, 2016). Hypothetically, this difference could potentially also lead to different evaluations or rankings in novel technologies. Patients would focus on pain relieving technologies, and the doctors on damage prevention. The rheumatologists see this as a limitation for patient participation. However, to contradict their arguments, the asymmetric information is not only way, but in two directions. As the vice-president of PARE clearly points out on the added knowledge by patients, '*we don't need more researchers, we don't need more doctors, we don't need more epidemiologists* [to come to a better decision]. *What we need here and what we miss here is the expertise of the person who lives with the disease. We need this expertise*' (PARE, 2016). Lastly, rheumatologist of Cochin hospital mentions that even though including patients in the decision making at the department would be possible, it would be time-consuming. This notion, in combination with his general attitude towards patient participation at community level, makes to believe that his perceived benefits do not outweigh the impracticalities, by far. Involving the patient would only be reasonable in case the new technology would harm the patient, or when the involvement itself would lead to better health outcomes. This would have nothing to do with the psychological empowerment or democratic reasoning, but merely clinical (Rheumatologist Cochin, 2016).

Underlying to these arguments is that the health professionals are convinced that they are sufficiently incorporating the patient perspective. They believe patient participation during the evaluation and uptake of novel technologies will not only be impractical, but is also unnecessary. Especially, rheumatologists are convinced they work in the best interest of

their patients. However, once again, without eliciting the patients' opinion or preferences, the rheumatologist may never know what is in the best interest of their patients.

5.3.4. The patient as stakeholder and their position on the participationladder

With healthcare being built on and around them, it cannot be denied that patient is a stakeholder. However, as described by Freeman (2010), an important distinction can be made between the external and internal stakeholder of an organization or business. An internal stakeholder is considered as part of the hospital, and has therefore much more influence and impact on the decisions made at collective of policy level in comparison to the external stakeholder. For example, the internal stakeholder has direct decision power when it comes to the uptake decision of the HandScan. Now, something peculiar is going on. Based on the findings in this study, when it comes to decision making at this level, of all stakeholders involved their stakeholder position, either external or internal, is self-evident. Except for the patient. Remarkably, according to the results of the interviews, each stakeholder in the procurement decision making process has a different perspective on the stakeholder position of the patient, there is no consensus. One argues that the patient is internal, the other argues that the patient is external. The subcommittee for investment and work, those who are assumed to give final approval in whether or not the HandScan will be purchased (at least in the official uptake process), attributes an external position to the patient. To quote rheumatologist of Saint Antoine: '*You will have to convince the committee, to convince that this will add value to your department, not value for the patient. Nobody cares for that*' (Rheumatologist Saint-Antoine, 2016). Based on interview input and on published HTA reports, CEDIT seems to share this perspective. Using words as 'cannot', referring to difficulties in organizing participation and with a general response of astonishment, it may be concluded that CEDIT attributes the patient an external stakeholder position as well, at least at this level of decision making. The rheumatologists involved in this study are somewhat peculiar, as they revealed a clear difference in what they say and what they actual do. On the one hand, they state things as 'nothing for the patient, without the patient', 'you need to involve the patient, you are not allowed to do without', 'the most important actor is the patient' (Rheumatologist Cochin, 2016) and 'we always take into account the patient preference' (Rheumatologist Saint-Antoine, 2016). On the other hand, when asked to the steps taken to arrange patient participation in the uptake processes of

new technologies, these appear to be non-existent. Therefore the attributed patient position is somewhere left in the middle. The EULAR as being a renowned and highly respected body by rheumatologists, is built on three equal pillars, namely health professionals, researchers and the patient/patient organization (Rheumatologist Cochin, 2016) (European League Against Rheumatism, 2016). As they explicitly consider the patient to be an equal in rheumatology care, a more internal position is attributed to the patient by EULAR. Especially PARE, the EULAR committee for all rheumatism patient organizations in Europe, stresses the internal patient position. To quote: '*The patient should participate in all the levels and should be part of the hospital. Not just as a consumer, coming from outside the hospital, asking for services. This is not the right way. The right way is that they should be involved in the hospital.[…] They should be equal partners in the hospital*' (PARE, 2016). Important to understand is that EULAR has no direct power in the procurement decision by the APHP, but has a substantial influence on the rheumatologists, who *do* have power in this procurement decision (Hemics, 2016). To summarize, Figure 6 shows who has the most decision power in the procurement process and the attributed patient position by all stakeholders.

Interesting is that those with the most decision power, attribute the patient an external stakeholder position. While those who are most in favour of patient participation, do not have any decision power. This may insinuate that it is unlikely for the patient to move to a higher rang on the participationladder. In order to enable patient participation at the procurement level of the APHP, there needs to grow a consensus on the internal stakeholder position of the patient among the other stakeholders. As long as the patient remains an external stakeholder to those who are in charge of the final procurement decision, participation as desired by Arnstein (1969) can never be achieved.

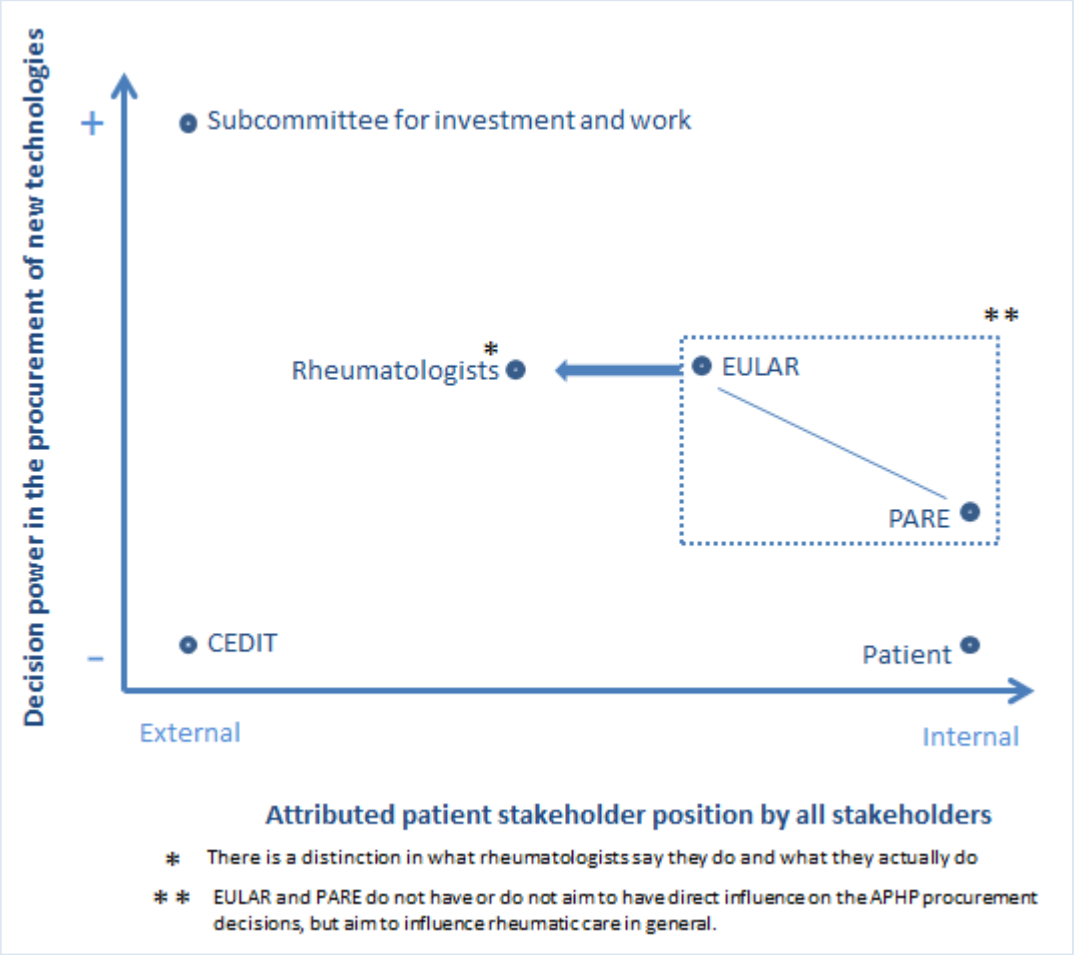

Figure 6: Attributed stakeholder position versus decision power

Theory of Arnstein is based on the idea that more participation is always better. Controversially, the opinions of interview participants in this study are not headed in the same direction. As a consequence, each stakeholder would place the desired position of the patient on a different step in Arnstein's ladder (manipulation, therapy, informing, consultation, placation, partnership, delegation and patient control). Whereas the external or internal stakeholder position reveals how the patient is perceived, the participationladder facilitates in which role the patient should play irrespective of their stakeholder position. Nevertheless, the location on the ladder seem to go hand in hand with designated stakeholder position given to the RA patients, including which position they designated to themselves. Among all stakeholders investigated in this study, those who placed the patient participation at a higher desired rang on the ladder tend to attribute the patient a more internal stakeholder position. The same argument holds the other way around, those who attribute the patient an external stakeholder role also have less desire in more patient participation in HB-HTA.

Figure 7 presents the desired participating role of the patient in the evaluation and purchase process according to the stakeholders involved, constructed from the findings of this study. The patient appeared to desire an equal partnership in any healthcare decision, including the technology uptake decisions (PARE, 2016) (European League Against Rheumatism, 2016). Therefore, together with PARE they can be placed on the sixth rang. As mentioned, PARE is the pillar within EULAR explicitly stressing the need to partner up with the patient. As there are also pillars stressing on the role of the researcher and health professional, PARE is placed slightly above EULAR as a whole organization. Rheumatologist of Cochin hospital is convinced that all the patients should be and want to be informed, but does not seem to be willing to offer active participation options. In contrast, rheumatologists of Saint Antoine hospital is towards active patient in the procurement process. Although, as he states, the culture of France is not prepared for full participation at this level, therefore, consultation will be the first step to make (Rheumatologist Saint-Antoine, 2016). Based on his reasoning of infeasibility and doubts regarding its added value, the speaker of CEDIT would not like the patient to participate in his work. With regard to the subcommittee for investment in work, according to the information gathered, they just seem not to be bothered.

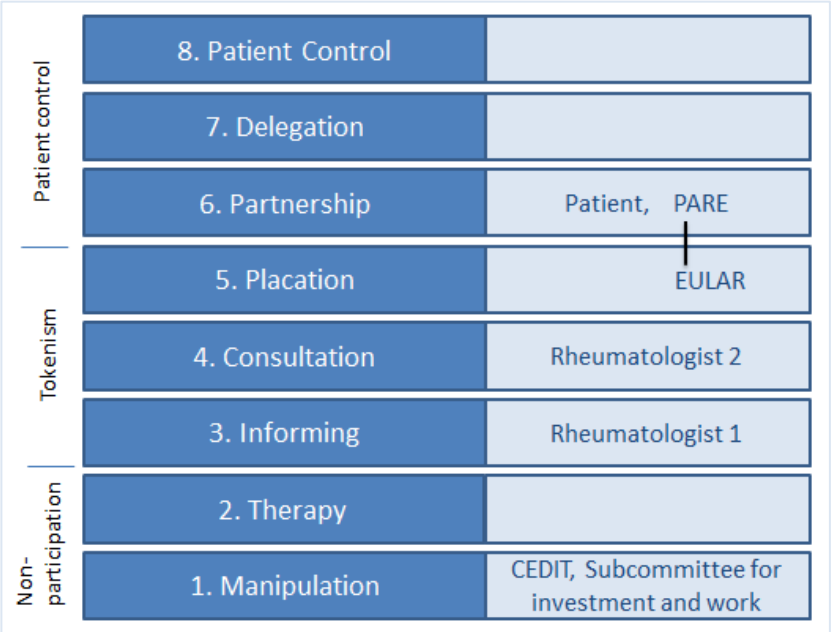

Figure 7: Desired patient participation according stakeholders

6. Discussion and Conclusion

This study aimed at revealing the patient position in the evaluation and uptake process of new healthcare technologies by the APHP. Here, focus was especially laid on the APHP-based HTA agency CEDIT. The primary answer to the research question '*What position do patients have in the hospital-based HTA agency – the Committee for Evaluation and Diffusion of Innovative Technologies (CEDIT), of the Assistance Publique – Hopitaux de Paris (APHP) and would more involvement be desired*?' is that there is no patient participation at CEDIT. However, based on data obtained during this case study, it seemed that there is no patient participation *at all* when it comes to technology evaluations and uptake decisions of the APHP. At least not, as revealed, in rheumatology care. Not through the official technology uptake process via CEDIT, nor in the unofficial process in which CEDIT's role is less prominent. According to this HandScan study, the identified problem for this lack of patient participation is the unshared desire for changing this level of patient participation among all stakeholders involved. This offers a secondary answer to the research question. On the one hand, those who desire a change towards more patient participation are the patient or patient representatives themselves. Among all the interviewees included in this study, they were the only one who perceive the patient as part of the hospital, and therefore as those who should have power or influence on the hospital policies and decision making. In other words, they are the only one who perceive the patient as internal stakeholder of the hospital in the evaluation and procurement of new technologies. On the other hand, those who perceive the patient as external stakeholder or as outsiders to the hospital, are the ones that *do* have the power in the decision making process. Yet, they do not desire a change in patient participation. In general it can be stated that they are convinced that their decisions are sufficiently made in the best interest of the patient already, and thus, more patient participation would be unnecessary. These different points of view are also reflected in the distinctive desired rungs on the patient participationladder. As a consequence, without any consensus on the internal stakeholder position of the patient and on the desired level of patient participation, it is unlikely that the APHP procurement process, with respect to involvement of the patient, will change in short notice.

According to the literature, the patient's opinion and satisfaction has become progressively important, and increasing emphasis has been placed on providing patient-focused

healthcare and ensuring patient involvement in the design of health services (Facey, et al., 2010) (Tritter & McCallum, 2006). The survey by the INAHTA confirms this trend of increased involvement of patients by the INAHTA agencies in their programs, and receives generally a positive response (Hailey, et al., 2011). Regardless, this study reveals that patient involvement is not ensured at the APHP when it comes to the procurement of the medical devices, like the HandScan. Nevertheless, patient participation at this HB-HTA level could come along with many opportunities. As elaborated upon, considering the judgment of HTAi, patient involvement within HTA is based on five main values, namely relevance, fairness, equity, legitimacy and capacity building (Cicchetti, Marchetti, Dibidino, & Corio, 2007). Some of these values could be confirmed in this study. For instance, RA patients do indeed have unique knowledge on their illness, and have personal experiences and values regarding their care. They will highlight other – and perhaps less clinical or economic - features of the HandScan. Therefore involving the patient in this HTA process is indeed relevant. Moreover, as the adoption of the HandScan by the APHP will affect their care through, for example, the changed relationship with rheumatologists, it would also indeed be fair and legit to engage patients in this purchase decision. As to say, in case patients are involved in the decision to evaluate the HandScan, or involved in the process of evaluating, it would add credibility and accountability to the recommendation of CEDIT, and also, once followed, to the final procurement decision by the rheumatologist, investment committee or the APHP in general. To summarize, in order to make healthcare indeed as patient-centered as generally aimed for, the patient needs to be included in the HB-HTA practice.

Irrespective of the general promotion of patient participation in HB-HTA as for example by the AdHopHTA, it cannot be denied that it has some barriers and obstacles. Especially since there are no guidelines available on how to organize this participation appropriately. Therefore, after finding a consensus by all stakeholders on the internal stakeholder position of the patient, there is a need to find ways in how this participation should be arranged. First you need to determine who this *patient* will be. Would we want that specific patient or patient representative that will be affected by the decision, for example the RA patient when it comes to a decision on the HandScan, or would we like a (future) patient representative from the general public? On the one hand, the RA patient is able to provide this unique knowledge and thus is the only one who could truly present this valuable additional

perspective when it comes to evaluating the HandScan. On the other hand, this RA patient might be subjective when it comes to ranking among technologies for evaluation. They would prefer to see a HandScan evaluated over a technology for another illness. Additionally, you need to be aware of the distinction between the proto-professional patient and the lay patient. Whose opinion do we value? Perhaps your first instinct would be to ask the patient organization for input. However, these patients are often highly educated according to the standards of the health professional (van de Bovenkamp, 2016). They have been thought to reason in line with their doctor, and no longer merely as a 'pure' lay patient. This could potentially threaten the idea of adding the patient perspective, instead of adding an educated-and-thus-semi-health-professional perspective. And last, some patients or patients groups might not be able to contribute due to their illness. Better said, some patients or patients will be too busy coping with their illness, and will not be willing to represent the patient population in the procurement decision of new technologies. Requiring increasingly participation of patients could therefore also place a burden to patients or their patient organization (PARE, 2016) (van de Bovenkamp, Associate professor, 2016). There are potentially no easy answers or solutions to these ethically challenging 'who is the patient'-issues.

To continue, once all stakeholders would find a consensus on who this patient with its internal stakeholder position is, another question remains on how this should be organized in terms of processes and decision power. Several authors have mentioned the different types of involvement, ranging from passive to active, and from consulting and co-decision making (Bridges & Jones, 2007). According to Arnstein (1969), participation without power is meaningless. As this study shows, the initial reaction to patient participation by each stakeholder is, as expected, positive. However, the gap remains between what should be done and what is actually done. In order to enforce true patient participation, we must ensure that processes of patient participation are systematic and effective. We should not want to have patients join the discussion table for the sake of having them there, neither do we want to ask their opinion without actually considering it. Basically, in order to make the patients' perspective count, we must find ways for the efficiently eliciting the patients' opinion and allow their perspective to possibly change the final technology evaluation or procurement decision. With regards to the HandScan, in case the RA patient would truly

express strong rejections against the purchase of this new technology, this opinion should not merely be considered, but should impact the recommendation by CEDIT or the purchase decision of the hospital. If not, like Arnstein (1969) argued, patient participation would indeed merely be a ritual.

6.1. Strengths and limitations

Since the information available on current or good practices of patient participation in HB-HTA is limited, any new insights are valuable. This study was able to obtain detailed and specific information on the practices of patient participation within CEDIT and APHP. Yet, this study did not only discover that there is not any form of patient participation in this technology procurement setting, but also was able to give an indication *why* there isn't. The use of the HandScan as a case study enabled to explore this adoption process by the APHP realistically. By gathering information from those people that indeed would be involved in this HandScan adoption process of the APHP, the interviewees are believed to be representative which raises the accuracy to this study. In order to safeguard the quality of the findings, several methods were applied, such as data triangulation, external supervising by Erasmus University, Oslo University and Hemics, and peer reviewing.

However, as with most studies, this study has also several limitations. In order to obtain an answer to the research question and its sub-questions, the choice was made to use qualitative research methods and a case study. In general, a limitation of this type of design is that generalizability or transferability cannot be claimed. Although based on this study it may be concluded that there is no patient participation at the level of CEDIT, these generalizing conclusions of non-patient participation cannot be made for *all* rheumatologists, *all* investment committees, or at the APHP in general. The same holds for the perceived patient position among stakeholders, as these cannot be transferred straightly to other institutions. Especially since some statements made could not be confirmed by others, due to the low number of interview respondents. If this study was to be repeated, inclusion of members of the hospitals' investment committees would be ideal. Moreover, in order to come to better generalizable results, more rheumatologists and other staff from different APHP sub-hospitals should be interviewed. Furthermore, a survey among lay-patients (and thus not proto-professional patients) on the values in their current care, their

opinion regarding the HandScan and the desire to participate in HB-HTA, might be appropriate.

During the process of this study, the researcher did an internship at Hemics, the manufacturer of the case study. The task as a researcher was not to promote this new device among the interviewees, but to gain knowledge on the practice of patient participation in their work. This was stressed before and during the interviews. However, the respondents might have been skeptical towards the researchers' intention and therefore potentially influenced their answers. Yet, as there was no direct interest from either side, this bias is considered to be limited.

The setting of this study was in France, and accordingly, (most of) the respondents were foreign. However, although the level of English for all respondents was considered fairly, it should be taken into account that for all English is not their mother language and that to a certain extent expressing yourself in a foreign language might be difficult. Although correcting for this expression bias impossible, it is good to keep this in mind.

6.2. Recommendations

Guided by the HandScan, the RA patient and rheumatology care, this study has acquired new practical insights on patient participation at technology evaluation and procurement processes at the clinical departments, investment committee, CEDIT, and the APHP in general. Although this research offered an indication why patient participation is not endorsed at APHP as recommended, more research would be needed to have these results confirmed. Additionally, as there is a lack of guidance on how patient participation should be organized, further research is suggested. This research should reveal who this patient should be, which role he is supposed to play, and which impact he should have in the final evaluation or procurement decision. These outcomes should then be developed into guidelines which can be used by hospitals and HB-HTA agencies to arrange appropriate patient participation.

Based on the results in this study, it is recommended to APHP and its staff to reconsider the patient-centeredness of the care they provide. The findings in this study indicate that there

are unshared ideas with respect to the stakeholder position of the patient, and the added values of involving them into the collective decision making. In order to become more patient-centered, steps towards more formal and systematic patients input need to be made. However, how to make these steps appropriately is, as mentioned above, dependent on further research.

This study also revealed the dual technology uptake processes of the APHP and the criteria on which a new technology currently is evaluated. This information could potentially be used by the industry to adapt their technology dissemination strategies. Based on this study, it is not recommended to approach the patient or patient organization, as they (currently) do not have any voice or decision power when it comes to the hospitals' technology evaluation process and procurement decision.

References

AFLAR. (2016, 06 11). *AFLAR*. Retrieved from Missions: http://www.aflar.org/missions

Angell, M. (1993). The doctor as double agent. *Kennedy Institute of Ethics Journal*, 279 - 286.

APHP. (2016, 02 09). *APHP International*. Retrieved from http://www.aphp.fr/international

Arnstein, S. (1969). A ladder of citizen participation. *Journal of the American Institute of Planners*, 216 - 224.

Assistance Publique - Hôpitaux de Paris. (2016). *Greater Paris University Hospitals.* Paris, France: AP-HP.

Babbie, E. (2003). *The practice of social research.* Belmont: Wadsworth.

Barna, A. (2013). Health Technology Assesment, Innovation and Research at AP-HP. Paris, France.

Baxter, P., & Jack, S. (2008). Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers. *The Qualitative Report*, 544- 559.

Bodeau-Livinec, F., Simon, E., Montagnier-Petrissans, C., Joël, M., & Féry-Lemonnier. (2006). Impact of CEDIT recommendations: An example of a health technology assessment in a hospital network. *International Journal of Technology Assessment in Health Care*, 161 - 168.

Boote, J., Telforn, R., & Cooper, C. (2002). Consumer involvement in health research: a review and research agenda. *Health Policy*, 213 - 236.

Bridges, J., & Jones, C. (2007). Patient-based health technology assessment: a vision of the future. *International Journal of Technology Assessment in Health Care*, 30 - 35.

Bryson, J. (1995). *Strategic Planning for Public and Nonprofit Organizations.* San Francisco, California: Jossey-Bass.

Buchbinder, R., Maher, C., & Harris, I. (2015). Setting the research agenda for improving health care in musculoskeletal disorders. *Nature Reviews Rheumatology*(11), 597 - 605.

CEDIT Assistance Publique - Hôpitaux de Paris. (2016, 04 10). *CEDIT The hospital-based HTA agency of the AP-HP*. Retrieved from CEDIT: http://cedit.aphp.fr/cedit-hta-agency/

CEDIT scientific secretariat. (2016, 05 18). Biomedical engineer - scientific secretariat CEDIT. (S. v. Beekhuizen, Interviewer)

Cicchetti, A., Marchetti, M., Dibidino, R., & Corio, M. (2007). *Hospital Based Health Technology Assessment World-Wide Survey.* Rome: Health Technology Assessment International.

Coulter, A. (2004). Perspectives on health technology assessment: Response from the patient's perspective. *International Journal of Technology Assessment in Health Care*, 92 - 96.

Creswell, J. (2003). *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches.* Thousand Oaks: Sage Publications.

de Bont, A., Severens, H., & Knies, S. (2016, 03 10). Diverse conversations. Rotterdam, the Netherlands.

Devlin, N., & Sussex, J. (2011). *Incorporating multiple criteria in HTA. Methods and processes.* London: Office of Health Economics.

Dill, W. (1958). Environment as an influence on managerial autonomy. *Administrative Science Quarterly 2*, 409 - 443.

Drummond, M., Schwartz, J., Jönsson, B., Luce, B., Neumann, P., Siebert, U., & Sullivan, S. (2008). Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Technology Assessment in Health Care*, 244-258.

Eden, C., & Ackermann, F. (1998). *Making Strategy: The Journey of Strategic Management.* London: Sage Publications.

Ehlers, L. (2012). Attitudes and barriers towards mini-hta in the danish municipalities. *International Journal of Technology Assessment in Health Care*, 271 - 277.

Ehlers, L., Vestergaard, M., Kidholm, K., Bonnevie, B. P., Jorgensen, T., Jensen, M., . . . Kjolby, M. (2006). Doing mini-health technology assessment in hospitals: A new concept of decision support in health care? *International Journal of Technology Assessmnet in Health Care*, 295 - 301.

Epstein, R., Fiscella, K., Lesser, C., & Stange, K. (2010). Why the nation needs a policy push on patient-centered healthcare. *Health Affairs*, 1489 - 1495.

European League Against Rheumatism. (2016, 06 03). *Structure*. Retrieved from http://www.eular.org/eular_structure.cfm

Evans, R. (1984). *Strained mercy: The economics of Canadian medical care.* Toronto: Butterworths.

Facey, K., Boivin, A., Gracia, J., Hansen, H., Lo Scalzo, A., Mossman, J., & Single, A. (2010). Patients' perspective in health technology assessment: A route to robust evidence and fair deliberation. *International Journal of Technology Assessment in Health Care, 3*(26), 334 340.

Freeman, E. H., Wicks, A., Parmar, B., & De Colle, S. (2010). *Stakeholder theory: The state of the art.* Cambridge: Cambridge University Press.

Gafni, A., Charles, C., & Whelan, T. (1998). The physician-patient encounter: The physician as a perfect agent for the patient versus the informed treatment decision-making model. *Social Science & Medicine*, 347 - 354.

Gagnon, M. (2014). Hospital-based health technology assessment: Developments to date. *PharmaEconomics*, 819 - 824.

Gagnon, M., Desmartis, M., Poder, T., & Witteman, W. (2014). Effectd and repercussions of local/hospital-bases health technology assessment (HTA): A systematic review. *Systematic Reviews*, 1 - 14.

Gagnon, M., Gagnon, J., St.Pierre, M., Gauvin, F., Piron, F., Rhainds, M., . . . Légaré, F. (2012). Involving patients in HTA activities at local level: A study protocol based on the collaboration between researchers and knowledge users. *BMC Health Services Research*, 1 - 7.

Gagnon, M., Lepage-Savary, D., Gagnon, J., St-Pierre, M., Simard, C., Rhainds, M., . . . Légaré, F. (2009). Introducing patient perspective in health technology assessment at the local level. *BMC Health Services Research*, 54 - 61.

Hailey, D., Corabian, P., Harstall, C., & Schneider, W. (2000). The use and impact of rapid health technology assessments. *International Journal of Technology Assessment in Health Care*, 651 - 656.

Hailey, D., Werkö, S., Bakri, R., Cameron, A., Göhlen, B., Myles, S., . . . Yothasamut, J. (2011). *Involvement of consumers in the HTA activities of INAHTA members.* Alberta, Canada: INAHTA.

Hämeen-Anttilla, K., Komulainen, J., Endlund, H., Mäkelä, M., Mäkinen, E., Rannanheimo, P., & Sipilä, R. (2016). Incorporating patient perspectives in health technology assessments and clinical practice guidelines. *Research in Social and Administrative Pharmacy*, 1 -11.

Haute Autorité de Santé. (2016, 06 07). *Outils, guides & méthodes*. Retrieved from HAS: http://www.has-sante.fr/portail/jcms/fc_1249605/fr/outils-guides-methodes

HBSP. (2006). *Havard Business Essentials, Decision Making: 5 Steps to Better Results.* Boston: Harvard Business Press.

Hemics. (2016, 05 26). Voortgangsgesprek. Eindhoven, The Netherlands.

HTAi. (2014). *Values and quality standards for patient involvement in HTA.* HTAi.

Jacob, R., & Battista, R. (1993). Assessing technology assessment. Early results of the Quebec experience. *International Journal of Technology Assessment in Health Care*, 564 - 572.

Johnson, G., & Scholes, K. (2002). *Exploring Corporate Strategy.* Harlow: Pearson Education.

Kidholm, K., Ehlers, L., Korsbek, L., Kjaerby, R., & Beck, M. (2009). Assessment of the quality of mini-HTA. *International Journal of Technology Assessment in Helath Care*, 42 - 48.

Kjeken, I., Dagfinrud, H., Mowinckel, P., Uhlig, T., Kvien, T., & Finset, A. (2006). Rheumatology Care: Involvement in medical decisions, received information, satisfaction with care, and unment health care needs in patients with rheumatoid arthritis and ankylosing spondylitis. *Arthritis & Rheumatism*, 394 - 401.

Kreis, J. (2013). Public engagement in health technology assessment and coverage decisions: A study of experiences in France, Germany, and the United Kingdom. *Journal of Health Politics, Policy and Law*, 89 - 122.

Mahmood, S., Lesuis, N., Van Tuyl, L., van Riel, P., & Landewé, R. (2015). Quality in rheumatoid arthritis care. *Best Practice and Research in Rheumatology*(29), 664 - 679.

Martelli, N., Bilaux, M., Borget, I., Pineau, J., Prognon, P., & van den Brink, H. (2015). Introduction of innovative medical devices at French university hospitals: An overview of hospital-based health technology assessment initiatives. *International Journal of Technology Assessment in Health Care*, 12 - 18.

Martelli, N., Lelong, A., Prognon, P., & Pineau, J. (2013). Hospital-based health technology assessment for innovative medical devices in university hospitals and the role of hospital pharmacists: learning from international experience. *International Journal of Technology Assessment in Health Care*, 185 - 191.

McGregor, M. (2006). What decision-makers want and what they have been getting. *Value in Health*, 181-185.

Moreira, T. (2014). Understanding the role of patient organizations in health technology assessment. *Health Expectations*, 3349 - 3357.

Mortelmans, D. (2009). *Handboek kwalitative onderzoeksmethoden.* Leuven/Den Haag: Acco.

Mwachofi, A., & Al-Assaf, A. (2011). Healthcare market deviations from the ideal market. *Sultan Qaboos University Medical Journal*, 328 - 337.

Nutt, P., & Backoff, R. (1992). *Strategic Management of Public and Third Sector Organizations: A Handbook for Leaders.* San Francisco, California: Jossey-Bass.

Ong, B. (1996). The lay perspective in health technology assessment. *International Journal of Technology Assessment in Health Care*, 511 - 517.

PARE. (2016, 04 26). Vice President PARE - EULAR. (S. v. Beekhuizen, Interviewer)

President AFLAR. (2016, 05 13). President AFLAR. (S. v. Beekhuizen, Interviewer)

Rappagliosi, A. (2010, 5 18). Policy challenges in HTA in Europe: the impact on patient access. Brussels, Belgium.

Rheumatologist Cochin. (2016, 05 10). Rheumatologist, Head of Rheumatology Cochin Hôpital. (S. v. Beekhuizen, Interviewer)

Rheumatologist Saint-Antoine. (2016, 05 12). Rheumatologist, Head of department Saint Antoine Hospital. (S. v. Beekhuizen, Interviewer)

Rodwin, V. (1992). *Public Hospital Systems in New York and Paris.* New York: New York University Press.

Saaid, H., Stewart, D., England, I., & Parmar, N. (2011). The impact of health technology assessment on decision-making processess in public versus not-for-profit private hospitals. *American Medical Journal*, 72 - 78.

Sampietro-Colom, L., Lach, K., Cicchetti, A., Kidholm, K., Pasternack, I., Fure, B., . . . Kiivet, R. (2015). *The AdHopHTA handbook: a handbook for hospital-based health technology assessment (HB-HTA).* Barcelona: The AdHopHTA project.

Sampietro-Colom, L., Lach, K., Pasternack, I., Wasserfallen, J., Cicchetti, A., Marchetti, M., . . . Ulst, M. (2016). Guiding principles for good practices in hospital-based health technology assessment units. *International Journal of Technology Assessmnet in Health Care*, 1 - 9.

Stake, R. (2000). Case studies. In N. Denzin, & Y. Lincoln, *Handbook for qualitative research* (pp. 434-454). Thousand Oaks California: Sage Publications.

Storhiem, K., & Zwart, J. (2014). Musculoskeletal disorders and the Global Burden of Disease study. *Annals of the Rheumatic Diseases*, 949 - 950.

Trappenburg, M. (2008). *Genoeg is genoeg.* Amsterdam: Amsterdam University Press.

Tritter, J., & McCallum, A. (2006). The snakes and ladders of user involvement: Moving beyond Arnstein. *Health Policy*, 156 - 168.

van de Bovenkamp, H. (2016, 04 22). Associate professor. (S. v. Beekhuizen, Interviewer)

van de Bovenkamp, H., & Zuiderent-Jerak, T. (2013). An emperical study of patient participation in guideline development: exploring the potential for articulating patient knowlegde in ecidence-based epistemic settings. *Health Expectations*, 942 - 955.

van de Bovenkamp, H., Trappenburg, M., & Grit, K. (2009). Patient participation in collective healthcare decision making: The Dutch model. *Health Expectations*, 73 - 85.

van de Bovenkamp, H., Vollaard, H., Trappenburg, M., & Grit, K. (2013). Voice and choice by delegation. *Journal of Health Politics, Policy and Law*, 57 - 87.

Van Onna, M., Ten Cate, D., Tsoi, K., Meier, A., Jacobs, J., Westgeest, A., . . . Bijlsma, J. (2015). Assessment of disease activity in patients with rheumatoid arthritis using optical spectral transmission measurements, a non-invasive imaging technique. *Annals of Rheumatic Diseases*, 1 -8.

Van Riel, P. (2014). The development of the disease activity score (DAS) and the disease activity score using 28 joint counts (DAS28). *Clinical and Experimental Rheumatology*(32), 65-74.

Van Veenendaal, H. (2004). Patiëntenparticipatie in richtlijnontwikkeling. In J. Everdingen, *Evidence-based richtlijnontwikkeling. Een leidraad voor de praktijk.* (pp. 48 - 62). Houten: Bohn Stafleu Van Loghum.

Yin, R. (1984). *Case study research: Design and Methods.* London: Sage Publications.

Appendix 1: DAS28 versus HandScan

DAS28 – Standard for monitoring RA

- Measurement of:
  - tender and swollen joint counts
  - blood marker for inflammation (ESR/CRP)
  - Patient global health assessment (VAS)
- Subjective elements: joint counts, VAS
- Only rheumatologist & trained nurses can do physical examination (work pressure & long waiting times)
- Time consuming
- Potentially painful
- Monitoring always requires face-to-face interaction, even in absence of other indications for a visit. Scheduled visits often do not coincide with episodes of active disease.

Hemics HandScan

- Uses optical light transmission – measures light absorption by blood to visualize joint inflammation in hands and wrists of RA patients.
- Operator independent:
  - Objective
  - Operated by an assistant resulting in reduced work pressure for the rheumatologist
- Quick: completed in a few minutes
- Examination is safe (unrestricted use) and painless
- Sensitive: a study showed[1] detection of subclinical inflammation
- Workflow concept (not clinically tested)
  - Assistant performs frequent monitoring using the HandScan and potentially a questionnaire
  - Only rheumatologist visit in case of active disease, or other indication for visit

[1] Van Onna, et al., *Ann. Rheum. Dis.* **75**, 511–518 (2016)

Appendix 2: Key principles for HTA

Developed by and quoted from Drummond and colleagues (2008).

Structure

Principle 1: The goal and scope of the HTA should be explicit and relevant to its use

'A detailed scoping document should be developed before initiation of the HTA process, with broad, multidisciplinary, stakeholder involvement. The document should focus on defining the questions to be addressed by the HTA, plus the link between the HTA and any decisions about the use of the technology'.

Principle 2: HTA should be an unbiased and transparent exercise

'Given the inherently complicated and controversial nature of HTA-based decisions and their importance to multiple decision makers and stakeholders, the HTA process is best conducted independently of the body that ultimately will be responsible for adopting, paying and implementing the HTA decisions. Furthermore, the HTA process and the detailed basis on which recommendations and decisions are made must be transparent'.

Principle 3: HTA should include all relevant technologies

'Because potential inefficiencies exist in all forms of healthcare, all health technologies should be potential candidates for HTA. Otherwise, decision making concerning the use of resources is likely to be distorted'.

Principle 4: A clear system for setting priorities for HTA should exist

'A clear process for prioritizing and selecting topics needs to be established, because in situations where not all technologies are assessed, there will be distortions in decision making about the investment and use of resources'.

Methods of HTA

Principle 5: HTA should incorporate appropriate methods for assessing costs and benefits

'Development and consistent implementation of rigorous, analytical methods is required to engender stakeholder and public trust in the process and its findings. This requires clarity of HTA process and methods, as well as access to experts with appropriate clinical and multidisciplinary methodological training'.

Principle 6: HTAs should consider a wide range of evidence and outcomes

'HTAs require use of data from experimental, quasi experimental, observational, and qualitative studies, integration of both endpoint and validated surrogate data, and assessment of the incremental impact of and trade-offs among multiple clinical, economic and social outcomes in clinically relevant populations'.

Principle 7: A full societal perspective should be considered when undertaking HTAs

'HTAs should adopt a broad societal perspective to optimize efficiency and societal benefit and to avoid and identify potentially distorted clinical decisions and health policies resulting from adoption of narrower perspectives used by various healthcare system stakeholders'.

Principle 8: HTAs should explicitly characterize uncertainty surrounding estimates

'All data are imperfect point estimates of underlying distributions that incorporate a variety of errors. All analytical methods are subject to biases and limitations. Thus, extensive

sensitivity analyses are required to determine the robustness of HTA findings and conclusions. The limitations of the analysis should always be acknowledged'.

Principle 9: HTAs should consider and address issues of generalizability and transferability

'Examination of the generalizability and transferability of HTA findings across clinical populations and policy relevant perspectives is required, given the inherent variability of disease, intervention responses, and outcomes across patients, populations, providers, healthcare delivery sites and healthcare systems'.

Processes for conducting HTA

Principle 10: Those conducting HTAs should actively engage all key stakeholder groups

'HTA programs should actively engage all key stakeholders in all stages of the HTA process, as this is likely to result in technology assessments of higher quality that are more widely accepted and stand a greater chance of being implemented. Moreover, such an open process will enhance transparency and trust in the process as stakeholders develop a greater understanding of the criteria and standards used'.

Principle 11: Those undertaking HTAs should actively seek all available data

'Those conducting HTAs should actively seek all available data, whether confidential or not. In situations where confidential data are used, confidentiality should be defined as narrowly as possible and efforts should be made to make it publicly available as soon as possible, in the interests of maintaining transparency and engendering understanding of and trust in decisions'.

Principle 12: The implementation of HTA findings need to be monitored

'Implementation of HTA findings need to be monitored, both to ensure that the original investment in conducting HTAs is valuable and to ensure that findings are being implemented in a fair and even-handed manner'.

Use of HTA in decision making

Principle 13: HTA should be timely

'HTAs should be conducted when they can inform key decisions in the diffusion and use of health technologies, and assessments should be kept up-to-date. To accomplish this goal requires timely conduct of studies by manufacturers and other advocates and, in selected circumstances, requires limited reimbursement conditional upon enrollment in a study to inform safety, effectiveness, and cost-effectiveness'.

Principle 14: HTA findings need to be communicated appropriately to different decision makers

'Given the multiple audiences for HTA findings, effective communication strategies need to be developed to meet the disparate needs of different users'.

Principle 15: The link between HTA findings and decision-making processes need to be transparent and clearly defined

'A clear distinction needs to be made between the HTA itself and the resulting decisions. The link between the assessment and the decision will be different in various settings, but in all cases it should be transparent'.