

Master thesis Health Sciences:

Patient preferences versus professional preferences in population screening technology

Patient centered decision making in the population screening for breast cancer

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Abstract:

Objective: New technologies are developed to compete with digital mammography in the detection of breast cancer in population screening. The adherence to the screening could increase, due to the comfort of these technologies and the lack of risks. A technology highlighted in this study is the Photoacoustic Mammography (PAM). The influence of different attributes on the implementation process is measured. The importance of efficiency, effectiveness, comfort, and risks will show what a new screening technology should achieve to be able to compete with digital mammography. And to what extent does the patient play a role in this process? Patient centered decision making is gaining attention but is this also the case in the preventive field of the population screening for breast cancer; does the patient prefer an active-, collaborative-, or passive role?

Methods: The analytic hierarchy process (AHP) is used. This tool for multi-criteria analysis can measure attributes at different levels, both quantitative and qualitative. Since there is uncertainty in the performance of PAM, three scenarios are created and are compared with the performance of digital mammography. 20 health care professionals and 142 patients are included in the study.

Results: The effectiveness of a screening technology is the most important factor in the choice for a screening technology for both health care professionals as patients. Surprisingly, comfort is valued as the least important factor in screening technology. There are discrepancies between the opinions of the patient and the health care professional on patient centered decision making. The client prefers a collaborative role, while the health care professional rather prefers a passive role for the patient.

Conclusion: The AHP results show that PAM is preferred over digital mammography by both professionals as clients if it performs at least equally as good as digital mammography, especially on the effectiveness. The effectiveness is the most important criterion in the choice for a screening technology in population based screening. Although the clients' opinion is important in the adherence to the population screening, the opinion of the radiologist is valued as the most important one. PAM could be a suitable screening technology in the future for clients with dense breasts.

Contents

Abstract:	
1. Introduction	
1.1. Digital mammography	
1.2. Photoacoustic mammoscope	7
1.3. The health care professional in medical technology as	sessment 8
1.4. Problem definition and research question	9
2. Methodology	9
2.1. The Analytic Hierarchy Process	9
2.1. AHP steps	
2.2. AHP: definition of the decision elements and construct	tion of the hierarchy11
2.2.1. Decision goal	
2.2.2. Alternatives	
2.2.3. Criteria	
2.2.4. Modeling uncertainty: expected performance of	PAM 13
2.3. Case selection and sampling	
2.3.1. Clients	
2.3.2. Health care professionals	
2.4. Interview questions	
2.4.1. Tumor characteristics	
2.4.2. Testing and adjustment of the interviews	
2.5. Data collection	
2.6. Data analysis	
3. Results	
3.1. Health care professionals	
3.1.1. Effectiveness scenarios for PAM	
3.1.2. Tumor characteristics	
3.1.3. Replacement of digital mammography for subgro	oups 19
3.2. Clients	
3.2.1. AHP outcome	20
3.2.2. Intention to adhere	
3.2. Subgroup analysis	
3.3.1. Non-adherent clients	23
3.2. Patient centered decision making	
4. Conclusion	
5. Discussion	

5.1.	Clients	27
5.1.2	1. N of clients	28
5.2.	Health care professionals	28
5.2.2	1. Health care professionals on patient centered decision making	29
5.3.	Interview methods	29
6. Reco	ommendations	30
7. Acknow	wledgements	30
Reference	es	31
Appendix	1: Organization of the population based screening for breast cancer	34
Appendix	2: AHP criteria	35
Appendix	3: Performance matrix	36
Appendix	4: AHP client hierarchy and AHP criteria	37
Appendix	5: Modeling uncertainty: expected performance of PAM	38
Appendix	6: Interview questions professionals (Dutch)	39
Appendix	7: Interview questions clients (Dutch)	41
Appendix	8: Difference in preference of professionals per region	43
Appendix	9: Shift in preference; effectiveness scenarios	44

1. Introduction

Patient participation in the decision making process and medical technology assessment (MTA) gains popularity in the medical world. This is emphasized by Wallner (2008) who states that: *"Patients should be the primary concern in any technology assessment"* [8]. When the patient becomes a stakeholder in the decision making process, new perspectives and points of view are added to address problems and wishes for health care [6]. The patient can fulfill the following roles in the decision making process:

- An active role, where the patient is the most important decision maker.
- A collaborative role, where both patient and physician decide which treatment is suitable.
- A passive role, where the physician decides what is best for the patient [9].

Patient centered decision making knows three levels; the micro-, meso-, and macro level[10]. Decision making at micro level takes place in the direct patient-doctor relationship when needs to be decided what treatment is most suitable for the patient. At meso-level patients recommend what technology should be implemented. At macro-level, this advice is taken into account in the creation of health policy and the decision to reimburse a certain treatment [10].

The field of interest of this study lies in patient participation at macro-level; the preference for screening technology in the population screening for breast cancer, which is a form of preventive health care. Here, it is increasingly advised for patients to play an active role in the decision making process as well as in hospital care [6]. Patient preferences in preventive health care and hospital care differ from each other. Since most patients in preventive health care often have no visible health issues, they have other preferences then patients who are already ill. Thus, the preferences of patients in preventive health care cannot be compared with those of an ill population. The preventive population screening for breast cancer is free of charge and participation is on voluntary base, therefore, it needs to be organized in such a way that the adherence is high. Patient centered decision making could play a role here.

High adherence in the population screening is important because breast cancer is a serious problem in the Dutch female population. About 1 out of 8 women will develop breast cancer in her life and the Dutch rates for breast cancer mortality are among the highest in Europe [11]. To decrease this mortality rate and increase the early detection rate, the population screening for breast cancer is implemented in 1990. Studies have shown that by systematically screening women in the age of 50-75 years old, the mortality rate due to breast cancer could be decreased [12].

The population screening for breast cancer cost around ξ 51.7 million on an annual base with an average costeffectiveness of ξ 2200,- per gained life year [13]. Two important health benefits arise from the population screening. First, early detection of breast cancer leads to a more effective treatment and an increase of the quality of life [14]. Second, early detection of breast cancer means a decrease in the mortality rate and the burden of disease. Breast cancer mortality rates measured in 2008-2009 are 31% lower compared to predictions of this mortality rate if the population screening would not have been implemented [15]. This is partly attributable to the way the population screening is organized. Every two years, 1.1 million women from the target population (age 50-75 years old) are invited to participate in the population screening. Mobile screening centers travel across the country to convenient locations which resulted in a high reach of women. This has resulted in adherence rates over 80% [16]. In other countries without mobile screening centers the adherence rates are much lower, averaging around 50% [16]. (A full description of the organization of the population screening for breast cancer can be found in appendix 1.)

Not all women are willing to adhere in the population screening for several reasons. The intention to adhere starts high in women who do not adhere in the screening yet, in the age group of 40-49 years old. The dropout rate among these women increases after they adhered to more screenings though. An important factor here is that some women believe to be more susceptible for breast cancer when they adhere in the population based

screening. Other women feel safe after a few screenings with a negative outcome and believe they cannot get breast cancer anymore [17-19]. Lower adherence to the population screening is also present in women older than 70 years [20, 21], foreigners who do not control the Dutch language [22], and women with chronic diseases, psychological problems or intellectual disabilities [23, 24]. Another reason for women not to adhere in the population screening is the screening technology that is used: the digital mammography.

1.1. Digital mammography

Digital mammography is the gold standard in detecting breast cancer. It is an effective method with average high values for sensitivity (85,7%) and specificity (92,3%) [25] It visualizes the breast tissue with X-radiation. (figure 1)[26]. Two images are taken per breast; one from a cranio-caudal and one from an oblique view. The obtained mammograms are assessed by a radiologist who score the mammograms based on the Breast Imaging-Reporting and Data System (BI-RADS). BI-RADS is a tool that is designed to systematically assess mammograms. The BI-RADS scores are given based on five tumor characteristics that are visualized by digital mammography:

- 1. Mass margins
- 2. Mass shape
- 3. Mass size
- 4. Mass location
- 5. Micro-calcifications

After the images are assessed, a BI-RADS score is assigned to the mammogram distributed in the following six categories:

- Category 0: No clear outcome of the images, further evaluation of the breast is required.
- *Category 1*: Negative outcome/no findings.
- Category 2: Benign findings.
- Category 3: A probably benign finding, short interval follow up is advisable.
- Category 4: Suspicious for malignancy, not typical. Biopsy is advisable.
- *Category 5*: High probability of malignancy, direct action is required [27].

If the mammograms show micro-calcifications or other abnormalities, this could indicate malignancy or a benign finding which could turn into malignancy. Further examination of the breasts is then required [28].

Although digital mammography is an effective way to detect breast cancer there are a number of disadvantages. The breast is compressed between two plates with a weight averaging between 12 to 20 kilograms per breast. Compression is necessary to decrease scatter of the radiation, decrease the amount of radiation and to create a clear image. This can lead to an uncomfortable and sometimes painful experience for the woman. 70% of all women experience a certain level of discomfort due to the compression. From this group, 65% of the women experience little to moderate pain and 35% experience moderate to severe pain. The mean pain level in this last group according to the Visual Analogue Scale (VAS) is a 7 out of 10, where 10 stands for the worst imaginable pain [29]. A study on the non-adherent women shows that the painful experience of digital mammography influence women negatively. From these non-adherent women, 14% says that the pain





Figure 1: Simplified display of digital mammography [2]

Figure 2: Digital mammogram image [3]

during the screening is so severe that they do not wish to participate anymore [30]. Another disadvantage of digital mammography is that abnormalities in the breasts are less clearly observable for women under 50, often with high breast density, and women who have gone through menopause. The specificity for these groups remains high, though the average sensitivity is reduced to an average of 67,3%. This results is a higher number of false negatives [25]. These groups of women need supplementary examination with ultrasound or MRI since their BI-RADS score is often 0. Finally, there is the radiation involved risk. 86 women out of 100.00 women develop radiation related cancers. Between 10 and 14 women out of 100.000 women participating in the screening die of radiation related cancers after a period of 20 to 30 years [31].

The adherence to the population screening remains high, despite the disadvantages mentioned above. This has led to the following results. After the implementation of the screening, the incidence rate of breast cancer has doubled but the mortality rate decreased by 25% [13]. Also, women who adhere to the screening have a 35% lower risk of dying and women who no longer die from breast cancer win on average 15 life years [15].

1.2. Photoacoustic mammoscope

Despite the health benefits of digital mammography, there are currently many developments going on in the field of breast cancer screening technology. New technologies are being created to cope with the disadvantages of digital mammography. It is expected that a screening technology which does not have those disadvantages will lead to a higher number of women adhering in the population screening.

The centre of Bio Photonic Imaging at the University of Twente is currently developing a new technology in the diagnosis and screening for breast cancer: the Photoacoustic Mammoscope (PAM) [32]. It uses laser detection which produces near infrared light, and an ultrasound device. The technology is based on the principle of vascularization around a tumor [32]. The blood vessels absorb the light of the laser which leads to thermal expansion in the blood vessels. This expansion is visualized by an ultrasound wave showing the vascularization (Figure 4). PAM is able to visualize all tumor characteristics that digital mammography can visualize except the micro-calcifications. It is expected that PAM has the ability to visualize three other tumor characteristics though: vascularization of the tumor, oxygen saturation of the vessels around the tumor, and stiffness and density of the mass. Vascularization shows the amount of blood vessels around a mass. A high amount of blood vessels could indicate malignancy. If PAM measures high levels of oxygen saturation in the blood vessels this could indicate malignancy as well [32]. To execute the screening, the woman lies in prone position with her breast hanging in an opening in the table. The breast is slightly compressed between two plates with an estimated weight of 4 to 5 kilograms (Figure 4). This compression is meant to prevent the breast from moving, more compression is not needed because it does not lead to a better image. The amount of pain or discomfort is therefore low, since the breasts are compressed guided by the pain sensation of the woman. Also, the woman is not exposed to ionizing radiation and the problems with visualizing dense breasts are overcome [5].



Figure 3: PAM image from cranio-caudal view [5, 7]



Figure 4: Prototype of PAM [5]

PAM is still in an early stage of development but the technique shows promising expected results on its performance. PAM is tested by Heijblom (2011) on 12 women diagnosed with a BI-RADS score of 4 or 5 in a diagnostic setting and will be tested on women diagnosed with BI-RADS score 1-3. The PAM images are compared with regular screening technologies such as digital mammography, and ultrasound. There are no tangible performance values available yet for both sensitivity and specificity, but it is expected that PAM will be a good adjunction to digital mammography and ultrasound [33]. Hilgerink (2009) has tested the added value of PAM in a diagnostic track. The outcome of this study is that the method of PAM is preferred above MRI, ultrasound and digital mammography based on the expectations of the performance by two expert teams [5]. Haakma (2011) used expert elicitation to compare PAM with MRI. In this study, PAM is expected to perform worse than MRI on several items which makes it the least preferred method [4]. It is expected to perform well on mechanical properties and the visualization of oxygen saturation though. The study ends with recommendations for PAM by the radiologists so it can be used as a possible replacement for MRI in the future.

If PAM will be used in the population screening for breast cancer it could influence the adherence of women, since the comfort level of PAM is much higher than the comfort level of digital mammography. This increase is especially expected in the group of non-adherent women who have experienced pain during digital mammography screening. Possibly, it is also a more suitable method for women whose breasts are not clearly visualized by digital mammography, such as women under 50 with high breast density.

1.3. The health care professional in medical technology assessment

Patients are not the only stakeholders in the decision making process. A multidisciplinary opinion needs to be developed in order to make an appropriate decision on the use of new technologies. That is why health care professionals play an important role in medical technology assessment [8]. In the population screening for breast cancer are various health care professionals who have an opinion about the screening technology. First, there are the health care professionals who directly work with the screening technology: the radiologists who assess the screening images, and the radiology assistants who operate the screening technology and instruct the patient. Second, the manager of screening, who organizes the screening and keeps track of the financial flow, is an important stakeholder as well. Third, advisory bodies such as the 'national evaluation team for breast cancer', LETB (landelijk evaluatieteam borstkanker), and the covering organization 'national centre for population screening reference', LRCB (landelijk referentiecentrum voor bevolkingsonderzoek). These organizations give advice to the Dutch government in the creation of policy and the implementation of new screening technologies. The Dutch government makes the final decision whether a new screening technology is implemented or not [13]. Here, adherence plays a role as well as for the patients, that is, in the intention to adopt a new screening technology that could be used in the population screening for breast cancer. The amount of influence that the patient has in this process, depends on whether the patient has an active, collaborative, or passive role. Currently, the health care professional decides what the best screening technology is for the patient. Thus, the patient has a passive role in the decision making process.

1.4. Problem definition and research question

Both digital mammography as PAM have both health benefits as disadvantages. The most optimal population screening program takes the patient preferences into account to increase the adherence. But there could be discrepancies between the preferred screening technology and the screening technology with the most health benefits. Since the success of a screening program depends on high adherence rates, it needs to be studied whether the screening technology is expected to affect the adherence to the population screening for breast cancer. Women have an active role in the population screening, after all, the screening is voluntarily and they decide whether they adhere to the screening or not. It is not clear though how the role of women is valued by the health care professionals who work in the population screening for breast cancer. PAM is expected to be able to compete with other technologies in a diagnostic setting, as assessed by professionals who work in the diagnostic setting. There is a difference though between the fields of hospital care and preventive health care in both patient population as in the valuation of the health benefits and disadvantages. This study will test whether the preference for PAM holds when it is used in the population screening for breast cancer for both women as the health care professionals who work in the population screening for breast cancer.

To be able to address all these items, two main research questions need to be answered:

(1) "Which breast cancer screening technology is most preferred by women and professionals in population based screening for breast cancer?"

And:

(2) "Do these preferences influence each other or the intention to adhere in the population screening for breast cancer?"

The research questions are divided into the following subquestions:

- 1. What attributes are important in the choice of a screening technology?
- 2. What is the preferred screening technology of women?
- 3. What is the preferred screening technology of professionals working in population screening for breast cancer?
- 4. How do professionals value the opinion of the women in their decision making?
- 5. Does the intention to adhere change when PAM would be used as a screening technology?
- 6. What role do the health care professionals and the women prefer in the decision making process?

2. Methodology

In this section, the methodology of the study will be discussed. The first half of the section is dedicated to a general overview of the used method. The second half of the section discusses the application of the method in for this study specifically.

2.1. The Analytic Hierarchy Process

To decide which breast cancer screening technology is preferred most by both patients and professionals, the Analytic Hierarchy Process (AHP) is used. It is developed by T. Saaty to systematically perform a multi criteria decision analysis [34]. It allows the user to assess multiple criteria by assigning weights to these criteria in a hierarchical structure. Pairwise comparisons between the criteria are made where upon these weights are converted into scores [34]. One of the major advantages of AHP is the ability to decompose the decision problem into smaller parts through the creation of a hierarchy. Since there are no correct or incorrect answers, AHP shows only the importance of each criterion, each assigned with a weight. AHP also offers the possibility to capture subjective, objective, quantitative, and qualitative measurements into one comparison matrix [35]. Furthermore, scenarios of uncertainty can be modeled and bias is reduced by calculating the inconsistency for each respondent [36]. All these advantages together with its' straightforwardness and ease of use makes the

AHP a suitable method to measure the preference of both technology end user and professional, and compare the differences in assessment of the different criteria.

2.1. AHP steps

The AHP is executed by systematically performing six steps (table 1) [36]. In step 1 the goal of the AHP will be determined, which is mostly a decision problem or endpoint that needs to be achieved. This step is broadened by the identification of stakeholders. In step 2 a hierarchical structure will be created. The decision goal is defined first by several criteria which should be met to reach the goal. The criteria are then deducted into several subcriteria which add another level to the hierarchical structure. In the final level of the structure the alternatives that will serve the decision goal are determined. These alternatives are the options the stakeholders can choose from. This completes the hierarchy, an example of an empty hierarchy is showed in figure 5.

Process steps	Description
1	Definition of the decision elements:
	Decision goal;
	Alternatives
	Criteria
2	Construction of the hierarchy
3	Deduction of the decision:
	Comparison of the importance of the criteria
	Comparison whether the alternatives meet the criteria
4	Synthesis: Calculation principal Eigen vector, and inconsistency
5	Sensitivity analysis
6	Final decision

Table 1: AHP steps



Figure 5: AHP hierarchy

The alternatives will be evaluated by comparing them pairwise on their performance on the different criteria, step 3. To make this comparison, an ordinal 9-point scale is used. A higher score means that one criterion is more important over another. A score from one to nine can be assigned to a criterion. Table 2 explains the meaning of the AHP score. Even numbers (2, 4, 6, and 8) can be assigned as well. These even values could be used when the respondent cannot decide between two of the odd values. When the criteria are compared to each other, the respondents need to score per criterion which alternative is favoured over another. The 9-point scale is now used to measure the preference for either PAM or digital mammography (figure 6). Here, a higher score means that one alternative is favoured over the other.

Score	Importance
1	Both criteria are equally important;
3	One criterion is slightly more important than the other;
5	One criterion is much important than the other;
7	One criterion is very much more important than the other;
9	One criterion is extremely more important than the other.

Table 2: AHP scores

Next, a comparison matrix will be created. This is the synthesis part, step 4. The goal of the synthesis part is to calculate to what level the different alternatives meet the goal. This is a value between zero and one. The alternative with the value that is closest to one is the most preferred alternative.

The participants in the AHP process need to be consistent in their decision making on the criteria and subcriteria, step 5. For example, there are three criteria, A, B, and C. The respondent prefers criterion A over criterion B, and criterion B over criterion C. One would expect that the respondent then prefers criterion A over criterion C. If the respondent answers that criterion C is preferred over criterion A, the answer of the respondent is inconsistent. Therefore, the level of inconsistency of each respondent will be calculated with the consistency index and consistency ratio. Saaty describes a desirable consistency ratio below 10% but an inconsistency level with a maximum of 20% is still considered to be acceptable. Whenever the level of inconsistency is higher, the respondent needs to be excluded from the study since this could bias the outcome of the AHP. Finally, when the calculation is complete, a decision can be made that meets the decision goal, step 6 [37].

2.2. AHP: definition of the decision elements and construction of the hierarchy

This section discusses the creation of the AHP framework specifically for this research. The first step of the AHP process if performed through the creation of the decision goal, the alternatives, and the criteria the alternatives should meet. The steps of this process are described in the following paragraphs.

2.2.1. Decision goal

The decision goal needs to be formulated clear and preferably in one sentence. Since in this study the decision needs to be made for the preferred screening technology, the decision goal is as followed: 'Choose the preferred breast cancer screening technology.'

2.2.2. Alternatives

Both methods discussed in the introduction, PAM and digital mammography will be used as alternatives in the hierarchy. In the decision for the preferred alternative in screening technologies, it is self-evident that the digital mammography needs to be taken into account since it is currently the only method used in the population based screening. The studies of Heijblom and Hilgerink show promising results in the preference for a diagnostic device; therefore PAM is taken into account. This technology is still in development but could be a potential screening device competitor with digital mammography [33, 38, 39].



Figure 6: visualization of a 9-point scale in AHP

Several other methods have been studied to compete with digital mammography and PAM in the decision making process. Magnetic Resonance Imaging (MRI) shows high levels of diagnostic accuracy for women at younger age and with high breast density. MRI is currently only recommended as a screening technology for young women with high risk of developing breast cancer though. It is also used as an adjunct to digital mammography when there is doubt considering its outcome, often when the woman has a BI-RADS score of 0. The article of Lord clearly states that MRI is not recommended as a screening device because the specificity is very low, resulting in high numbers of false positives. Therefore, the MRI is excluded from this study. [40, 41]. The same issues are described for ultrasound [41]. This is a method which can detect breast cancer in a very accurate way but it is often used adjunct to MRI and digital mammography.

A method which is currently tested to be implemented as a screening device in the United Kingdom is the Multistatic Array processing for Radio wave Image Acquisition (MARIA). It gained a lot of media attention because of its' possible revolutionary results, speed, and comfort. This would have been an optional alternative were it not for the lack of scientific evidence on the performance of MARIA. Because information on the performance is prohibited to the public MARIA is excluded as an alternative [42].

2.2.3. Criteria

A literature study has been performed to identify relevant criteria to add in the AHP. No previous research has been performed on patient preferences in population based screening for breast cancer. The criteria are therefore selected from literature on patient preferences for preventive colorectal cancer screening [1, 6, 7], the expected performance of PAM and the preferences for this method [4, 5]. Finally, national and international guidelines on the organization of the screening and what criteria a screening device should meet to be sufficiently used as a preventive screening technology are studied [13, 14, 26, 43]. Overlapping criteria are synthesized into one criterion. Redundant criteria are deleted from the list. This list is discussed with the tutors, representatives from the population screening for breast cancer organization, and the creators of PAM. More criteria are synthesized and new criteria are added. This completes the hierarchy (figure 7).



Figure 7: AHP hierarchy to choose the preferred breast cancer screening technology

2.2.4. Modeling uncertainty: expected performance of PAM

PAM is still in a development stage, no concrete clinical data are available on the performance of the device yet. The performance of PAM needs to be added in the AHP for the stakeholders to be able to make a decision on the most preferred screening device. Therefore, assumptions on the expected performance of PAM are made based on the studies of Haakma and Hilgerink. These assumptions are converted into three performance scenarios, (1) the assumed worst, (2) the assumed average, and (3) the assumed best scenario. In the AHP, the respondents can then answer to what level they are willing to accept a certain level of sensitivity and specificity. For sensitivity these values are: 50%, 70%, and 85%. For the specificity these values are: 45%, 75% and 90%. In the AHP is asked if the respondents prefer digital mammography or PAM for each scenario. These results will be goal setting for the performance of PAM; the results will show what the minimum level of effectiveness, that is, sensitivity and specificity, PAM must achieve before it is accepted by the respondents. (For calculation and choice of these scenarios see appendix 3.)

2.3. Case selection and sampling

The following paragraphs describe the population used in the study, and the sampling methods that are used.

2.3.1. Clients

To be able to measure the patient preferences, patients need to be included in the study to decide what screening technology has their best interest. The women who undergo the screening cannot be labeled as patients since, in fact, they are not ill. The women are in this case the clients who participate in the population screening for breast cancer. Therefore the term 'client' will be used instead of patient.

The sample of clients contains women aged between 50 and 75 years old. This group of women will be included since this is a sample of the population who is invited for the population screening for breast cancer, and is therefore representative for this population [16]. Furthermore, a sample of women aged between 40 and 49 years old will be included. This subgroup is excluded from the population screening, but will be added in the study as well. This is done because it is expected that PAM will have high performances in the detection of breast cancer in younger women [38, 39]. Since there is also a difference in the intention to adhere in the population screening between women younger and older than 50 years old, a subgroup analysis will show whether the preference and intention to adhere is different if another screening technology is used instead of digital mammography.

A random sample of 600 women is drawn from the 1.1 million women summoned to participate in the screening. Using a rule of thumb, it is 99% certain that this sample will be representative for the population with a margin of error of 5% [44]. The sample of women will be derived from the company Survey Sample International (SSI). This company has a database which can represent different populations. This database is representative for the target population.

Women who suffer from breast cancer or have had a positive mammogram are excluded from the population screening since they will receive other tailored diagnostic interventions. Therefore, these women are excluded from this study, since the aim is to measure the preference of women who adhere in the population screening for breast cancer [17]. Women who do not speak or write Dutch are excluded as well since they are not able to fill in a questionnaire. It is not possible to prevent bias in the sample, especially in the intention to adhere in the screening. This is described by Drossaert, who states that: *"Women who already refuse to adhere in a screening program, also refuse to adhere in a questionnaire which could lead to results that are too positive [17]."*

2.3.2. Health care professionals

Besides the technology end users described in the previous paragraph, other stakeholders are added in the study as well. The health care professionals as describes in chapter 1 will be approached to participate in the study. The preference for a screening technology is measured in the field of preventive health. The population screening for breast cancer is organized by a national institution divided in five regions. 'Bevolkingsonderzoek Oost', the local instance which organizes the population screening for breast cancer in the counties of Overijssel and Gelderland, is approached to provide the sample of health care professionals. Within 'Bevolkingsonderzoek Oost' are three sub regions from which the work is performed and coordinated; Nijmegen, Apeldoorn and Enschede. Table 3 shows the health care professionals who have agreed to participate in the study.

Profession				Activity
Radiologists	(N=4)			User
Radiology as	sistants	(N=13)		User
Advisor of N=2)	LRCB	(radiologist/resea	rcher,	Advisory body to the RIVM
Manager	of	screening	at	Organizer/payer of population screening for breast
'Bevolkingso	nderzoe	ek Oost' (N=1)		cancer

Table 3: Profession and activities of the different stakeholder groups

The sample of the different stakeholder groups is small but the opinion of the respondents of each profession group is expected to be representative for the entire population of 'Bevolkingsonderzoek Oost'. Radiologists from all three sub regions are represented in the sample of professionals. From each region a coordinating radiologist has responded. One of the radiologists is also a member of the board of the Dutch radiologists council (NVVR, *Nederlandse Vereniging Voor Radiologen*), which is also an advisory body to the LETB, and Dutch government. The opinions of these radiologists are expected to be representative for a large group of radiologists. The respondents from the group of radiology assistants are very diverse. The groups of radiology assistant vary in region, age and years of experience. One of the radiology assistants is a member of the employees' council which also enlarges the representative of this sample.

Chapter 1 describes the Dutch government as an important stakeholder in the decision making process. The Dutch ministry of health (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) is approached to participate in the study. Unfortunately, the RIVM explained that they have hardly any knowledge of health care technologies and they mainly follow the advice of the LRCB. Therefore, they are not willing to participate in the study. The Dutch government thus needed to be excluded as a stakeholder in the decision making process.

2.4. Interview questions

The valuation of patient centered decision making cannot be measured with the AHP. Therefore, the respondents need to answer some closed ended questions about this topic as well. Both health care professionals as clients answer questions about how they value the clients' opinion. Next, they need to answer which stakeholder opinion they find most important in the choice for a screening technology. For the health care professionals a validating question for the effectiveness is added, where they are asked if they are willing to accept PAM at a certain level of effectiveness. Here, sensitivity and specificity will be combined to prove at what level of effectiveness the respondent is willing to adopt PAM. It also shows whether the respondent is consistent in the answers of both the AHP as the other questions. The complete closed ended interviews can be found in appendix 6 and 7.

2.4.1. Tumor characteristics

An important factor of the effectiveness of a screening technology is the visualization of different tumor characteristics mentioned in the introduction. These characteristics are important to specify between benign and malignant tumor types. Concrete data on the performance of PAM on these tumor characteristics is still

missing. The health care professionals however, are asked to decide the importance of the visualization of each tumor characteristic. Some new features of PAM such as oxygen saturation and stiffness and density of the tumor mass will be added to the tumor characteristics that PAM and digital mammography measure. Future research will then reveal whether PAM is truly suitable as a screening technology.

2.4.2. Testing and adjustment of the interviews

Three test interviews for the professionals are performed; one with a master student health sciences, and two interviews with radiology assistants. Furthermore, the questions have been judged by an expert in AHP and the coordinator 'scientific research' from 'Bevolkingsonderzoek Oost'. The interviews are tested on; difficulty, duration, validity, and skills of the interviewer.

There is a difference in the expertise of each stakeholder group, therefore, the interviews needed to be adjusted. The item 'tumor characteristics' is assessed as 'too difficult' by both the student as the radiology assistants. Only a radiologist can interpret the importance of different tumor characteristics, since they need to perform the diagnosis. Consequently, this item is only answered by the radiologists.

The hierarchy for the client is simplified. The criterion 'efficiency' is deleted from this hierarchy, since the client cannot judge items such as costs and ergonomics for the professionals. The duration of the scan and the number of radiology assistants are considered to be important for the client, therefore, it has been added to the criterion 'comfort'. The complete hierarchy for the clients can be found in appendix 4.

2.5. Data collection

The interviews of the health care professionals and clients are approached in a different way. The health care professionals are interviewed face to face. This is possible since the sample of professionals is small. By interviewing face to face, the respondent is forced to answer all the questions. Since PAM is a new technology, the health care professionals need some explanation about the technology. Before the interview starts, the respondents listen to a short introduction by the interviewer. Then, the respondent has the possibility to ask questions to complement the image they have on PAM and thus enlarge the ability to judge the technology. The AHP hierarchy is transferred into the program 'Expert Choice Desktop'. The pairwise comparisons are immediately added in the program so the result for each respondent becomes immediately clear. The analysis of the other interview questions is performed by Microsoft Excel. The client interviews are created with the online survey program 'Survey Monkey'. The sample of 600 respondents is too large to interview each respondent face to face. A company is hired to sample 600 women who are representative for the population. After the data is collected, the data is transferred to Microsoft Excel as well to be able to compare the results with the answers of the professionals.

2.6. Data analysis

To answer the research questions, data analysis needs to be performed. The AHP steps are performed with the program 'Expert Choice Desktop' which performs the calculations. These calculations can be transported to Microsoft Excel for further data analysis. The outcome of the AHP of both clients as professionals will be analyzed and compared. A subgroup analysis will be performed to detect significant differences between the preferences of the subgroups. The effectiveness will be analyzed more extensively, since different scenarios for the performance of PAM are created. The shift in preference for PAM and digital mammography will be calculated which shows the minimum performance that PAM should have, before it is accepted as a screening technology in population based screening.

The different tumor characteristics will be weighted and valued on their importance. The tumor characteristics are assessed by six radiologists. A box plots will visualize the spread of the tumor characteristics to show if there is any variance within the different radiologists.

The group of women is analyzed by descriptive statistics to show the characteristics of the sample population. The AHP outcome will be discussed as well. The AHP outcome of the women will be compared with the AHP outcome of the professionals. Finally, the patient centered decision making will be analyzed. Non-parametric tests will show whether the difference in valuation of the clients' opinion is significant. From these test can be concluded what the preferred role of the women is in the decision making process.

3. Results

First, the preference of the professionals will be analyzed. The client preference will be discussed next, and a group decision will be made. Finally, the analysis of the importance of patient centered decision making in population screening for breast cancer will be presented.

3.1. Health care professionals

Individual interviews are held with 19 professionals from the field of population screening for breast cancer. Digital mammography is compared with PAM. In the 'effectiveness' section the three scenarios of the assumed performance of PAM are used to be able to compare PAM with digital mammography on its performance.

Figure 7 shows a graphic representation of the preference of the professionals for digital mammography and PAM. Even though the performance of PAM2 is better than PAM1, there is no large difference in the preference for one of these methods. PAM3 is preferred over digital mammography with a score of 38,6%.



Figure 7: overall preference of the professionals for PAM or mammography

To understand how this score came about, the AHP score per criterion and subcriterion is presented in table 3. The first two rows show the weight of the criteria and subcriteria. The first column shows the alternatives with the AHP value. This value represents the preference for each alternative. The other columns show the AHP values for the alternatives per subcriterion. From this table can be concluded that PAM3, which represents the best performance scenario on effectiveness, has a slight preference above digital mammography to be used in the population screening for breast cancer with AHP scores of 0,372 (PAM3) and 0,347(digital mammography). PAM3 is assumed to perform better than digital mammography in the criteria effectiveness, comfort, and risks. Digital mammography performs better on the criterion 'efficiency'. PAM1 and PAM2 both are the least preferred methods, due to the performance on the criterion 'effectiveness'.

Effectiveness is by far valued as the most important criterion with an AHP score of 0,637. The sensitivity of the screening technology (subcriterion 2.1) is valued as the most important subcriterion with an AHP score of

0,742. The second most important criterion is efficiency with an AHP score of 0,151. Digital mammography performs better at all the efficiency subcriteria except on subcriterion 1.2 (purchase- maintenance cost/refractory life). Digital mammography especially performs better on the subcriteria 'scan time' and 'ergonomics'. The second least important criterion is comfort. Here, the compression of the breast is valued as the most important subcriterion because this leads to the most discomfort of the client. The criterion 'risks' is valued as the least important. An explanation for the low AHP score of 0,096 could be that both digital mammography as PAM have no or very low risks.

Combined outcome of digital mammography versus PAM3									
Criteria	Efficienc	y:			Effectiven	ess:	Comfort:		Risks:
	0,151				0,637		0,117		0,096
Subcriteria	1.1	1.2	1.3	1.4	2.1	2.2	3.1	3.2	4.1
Alternatives	0,182	0,118	0,248	0,452	0,742	0,258	0,639	0,361	1
Digital	0,406	0,122	0,601	0,323	0,393	0,409	0,052	0,406	0,214
mammography									
0,347									
PAM3	0,199	0,293	0,133	0,223	0,455	0,445	0,316	0,192	0,255
0,372									
PAM2	0,199	0,292	0,133	0,223	0,111	0,106	0,316	0,192	0,255
0,160									
PAM1	0,195	0,292	0,132	0,231	0,041	0,040	0,316	0,210	0,277
0,121									

Table 3: AHP outcome: values for the alternatives, criteria and subcriteria

3.1.1. Effectiveness scenarios for PAM

The three scenarios for PAM are each individually compared with digital mammography on the criterion 'effectiveness'. This is presented in table 4. Digital mammography is preferred over both the assumed worst, and assumed average scenario of PAM with AHP scores > 0,80 for digital mammography. When PAM performs at its assumed best, that is, with a sensitivity of 85% and a specificity of 90%, it is slightly preferred over digital mammography with AHP values of 0,543 for sensitivity and 0,52 for specificity. The shift in preference for a screening method lies at the AHP value of 0,50. The respondent values both alternatives as equally good at this point. The preference for PAM is only slightly higher than mammography at the best scenario, thus can be concluded that before PAM is considered as a screening method in the population screening, its performance should at least equal the performance of digital mammography.

After the respondents finished the AHP questions, a validating closed ended question is asked to measure whether the respondents are intended to consider PAM at certain level of sensitivity and specificity (figure 8). A group of 84% of the professionals is willing to consider PAM in the most positive scenario; a sensitivity of 85% and specificity of 90%. The average scenario has a much lower level of support, only 21% is willing to consider PAM here and none of the respondents is willing to adopt PAM at the worst performance scenario. This validated that PAM must perform at least as good as digital mammography before the health care professional is willing to consider the adoption of PAM.

AHP value			AHP value		
Sensitivity PAM	PAM	Mammography	Specificity PAM	PAM	Mammography
50%	0,111	0,889	45%	0,111	0,889
70%	0,17	0,83	75%	0,155	0,845
85%	0,543	0,457	90%	0,52	0,48

Table 4: criterion effectiveness: the assumed worst, average, and best scenario of PAM versus digital mammography

3.1.2. Tumor characteristics

In this section the radiologists are asked how they value the different tumor characteristics on a scale from 1 (absolutely not important) to 10 (extremely important) in the diagnosis of breast cancer (figure 9). The two most important criteria are 'mass margins'(mean score 9) and 'micro-calcifications' (mean score 8,8). The criteria 'mass size', 'vascularization', and 'location' have the largest spread with standard deviations of σ =2,1 (mass size), σ =2,2 (vascularization), and σ =2,2 (location). This shows that there seems to be disagreement within the group of radiologists whether a tumor characteristic is important or not. The extra features that PAM has over digital mammography are valued as not important in the screening process with mean scores of 3,8 (oxygen saturation), 2,5 (stiffness and density of the mass).



Figure 8: intention to adopt PAM based on scenarios of performance on sensitivity and specificity



Figure 9: importance tumor characteristics

3.1.3. Replacement of digital mammography for subgroups.

The professionals are asked in the close ended questions if they would prefer another screening technology for certain subgroups of women. 75% of all professionals would like to see digital mammography replaced by another screening technology for women with dense breasts. In this group, digital mammography cannot visualize the breast tissue properly. Many women with dense breasts need supplementary screening of their breasts in the hospital which could cause unnecessary stress. The other 25% of the professionals only want adjunct technology to visualize the breasts. They do not want to replace digital mammography.

3.2. Clients

A total of 851 questionnaires are sent to the selected population of clients; women aged between 40 and 75 years old. The clients are excluded on incompletion of the questionnaire, a positive mammogram or being treated for breast cancer, and inconsistency in the AHP questions.



Figure 10: included and excluded women

A total of 142 clients are included in the analysis. The mean age of these clients is 52,4 years with a standard deviation of 8,64 and a range between 40 and 74 years. Table 5 shows the education the clients had. Most clients completed high school (middelbaar onderwijs, 38,7%), community college (MBO, 31,7%), and a Bachelor's degree (HBO, 23,2%). Although a majority of the clients is lower educated, this is representative for the Dutch female population for that age group, where only 17%-23% of the clients are higher educated [45]. The level of inconsistency is not related to the client's education. An analysis of the inconsistent clients using a two tailed t-test shows there is no significant difference in the educational level between the in- and excluded clients (P=0,998).

The adherence to the population screening is also measured. 41,5% of the clients are younger than 50, and therefore not yet invited to adhere in the screening. From the clients who can already adhere in the screening (N=83) 89,2% adhered to all the screenings they have been invited to. Only 2,8% of clients have never responded to the invitation to adhere in the population screening.

Education level included of	clients		Education level excluded clients
	Frequency	Percent	Percent
Basisonderwijs	4	2,8	6,8
Middelbaar onderwijs	55	38,7	34,2
МВО	45	31,7	33,7
НВО	33	23,2	20,3
WO	5	3,5	5,1
Total	142	100	100

 Table 5: Education level women

	Frequency	Percent
Every screening	74	52,1
More than half of the screenings	3	2,1
Less than half of the screenings	2	1,4
None of the screenings	4	2,8
I cannot adhere in the screening yet	59	41,5
Total	142	100,0

Table 6: how often did you adhere to the screening?

3.2.1. AHP outcome

Both figure 11 and table 7 show the outcome of the AHP filled in by the clients. This preference is comparable to the professionals' preference. PAM3 is preferred over digital mammography with AHP values of 0,340 (PAM3) and 0,281 (digital mammography). Both PAM1 and PAM 2 are less preferred than digital mammography. Calculation of the preference for a screening method considering the main criteria shows that PAM3 is assumed to perform better on only one criterion, 'effectiveness'. The AHP values are 0,435 (PAM3) and 0,290 (digital mammography). PAM is expected to perform worse on both 'comfort', (AHP values of 0,244(PAM) and 0,253 (digital mammography)) and risks (AHP values of 0,239 (PAM) and 0,284 (digital mammography). The criterion 'effectiveness' is valued as the most important though, with AHP value 0,513, therefore, PAM is the preferred method over digital mammography. The risks of the screening are second most important with an AHP value of 0,280, and 'comfort' is valued the least important with AHP value 0,204. Sensitivity (subcriterion 1.1) is considered to be most important with an AHP value of 0,673. The compression of the breast is the most important subcriterion within 'comfort', with AHP value 0,288.



Figure 11: overall preference of the clients for PAM or mammography

Mammography versus PAM							
Criteria	1. Effectiveness: 0,513		2. Comfort : 0,204				3. Risks : 0,280
Subcriteria Alternatives	1.1 0,673	1.2 0,327	2.1 0,288	2.2 0,268	2.3 0,255	2.4 0,175	3.1 1
Mammography 0,281	0,307	0,254	0,154	0,237	0,372	0,284	0,284
PAM3 0,340	0,392	0,523	0,282	0,254	0,209	0,239	0,239
PAM2 0,194	0,169	0,111	0,282	0,254	0,209	0,239	0,239
PAM1 0,182	0,132	0,111	0,282	0,254	0,209	0,239	0,239

Table 7: AHP outcome: values for the alternatives, criteria and subcriteria

After the AHP is finished, the clients are asked which of the three criteria is most important to them when they intend to adhere in the screening (table 8). The order of importance remains the same for both the validating questions as the AHP outcome. 'Effectiveness' is the most important criterion, followed by 'risks', and 'comfort' is valued as the least important criterion. There are differences between the validating question and the AHP outcome though. 73,9% of the clients answered in the validating question that they find 'effectiveness' the most important criterion. In the AHP outcome, 70,4% of the clients value the 'effectiveness' as the most important criterion. 14,1% of the clients find 'risks' the most important criterion in the validating questions versus 21,5% in the AHP outcome. Finally, 12% of the clients find 'comfort' the most important criterion in the validating question versus 8,5% in the AHP outcome. A Chi-square test shows that this difference is not significant (P=0,700). Spearman's Rho is used to calculate the correlation between the ranks that are assigned to the criteria in the AHP and in the closed ended question. The outcome (Spearman's Rho= 0,005) shows no relationship between the ranks assigned in the AHP and in the closed ended question.

	Validating ques	stion	AHP outcome		
	Frequency Pe	rcent	Frequency Percent		
Effectiveness	105	73,9	100	70,4	
Comfort	17	12,0	12	8,5	
Risks	20	14,1	30	21,5	
Total	142	100	142	100	

Table 8: the most important factor to adhere in the population screening; validating question vs. AHP outcome

3.2.2. Intention to adhere

The clients are then asked if they would attend to a screening with digital mammography, and to a screening with PAM3. For digital mammography, 65,5% has the intention to definitely adhere in the screening and 19,7% will probably adhere in the screening (table 8). The cumulative percentage of these groups is 85,2%. None of the respondents has the intention definitely not adhere in a screening program were digital mammography is used.

The intention to adhere in a screening program were PAM3 is used is slightly different than in a screening were digital mammography is used. 57,7% will definitely adhere in a screening were PAM3 is used. This value is lower than the intention to definitely adhere in screening with digital mammography. 26,8% will probably

adhere in a screening were PAM3 is used. Although the number of clients who will definitely intend to adhere in a screening with PAM3 is lower than the intention to adhere in a screening were digital mammography is used, the cumulative percentage for these two groups is 84,5% (57,7%+26,8%). The percentages of clients who do not know whether they will or will not adhere to the screening and who will probably not adhere in the screening is the same for both PAM3 as digital mammography, 11,3%. A Wilcoxon Signed Ranks test is performed (P= 0,290), showing that there is no significant difference in the intention to attend to the screening when either PAM3 or digital mammography is used. Only one person will definitely not attend to the population screening for breast cancer if PAM3 is used. The respondent finds it a waste of money to implement a new screening technology.

A final important item is the correlation between the AHP scores for PAM and digital mammography, and the intention to adhere when the client is invited to a screening where either PAM3 or digital mammography is used. A Spearman correlation is used, which shows a non- significant weak relationship between the AHP score for PAM3 and the intention to adhere to a screening with PAM3 (Spearman's Rho= 0,051). There is also a weak negative relationship between the AHP score for digital mammography and the intention to adhere to a screening with digital mammography (Spearman's Rho = -0,128).

	Digital mamn	nography	РАМЗ		
Intention to adhere?	Frequency	Percent	Frequency	Percent	
Definitely yes	93	65,5	82	57,7	
Probably yes	28	19,7	38	26,8	
I am not sure	16	11,3	16	11,3	
Probably not	5	3,5	5	3,5	
Definitely not	0	0	1	,7	
Total	142	100,0	142	100,0	

Table 9: intention to adhere to the population screening per screening technology

3.2. Subgroup analysis

The results of both professionals as clients point in the direction of PAM3 as most preferred screening method in the population based screening. The difference in the preference between the subgroups is presented in the box plot on page 24 (figure 13). Only one manager of screening is included in the study, the AHP values are therefore presented as lines instead of box plots. The box lot visualizes the difference in preference between subgroups. The clients are most positive about PAM3, the radiologists the least positive. The preference of the radiology assistants has the widest range, meaning that there are interdisciplinary differences in this group. The clients are less negative about PAM1 and PAM2 than al groups of professionals. A Kruskal-Wallis test shows that the difference between groups is not significant for digital mammography (p=0,123), but it is for PAM3 (p=0,044), PAM2 (p=0,024), and PAM1 (p=0,026) at a significance level of α =0,05.

Figure 12 shows the preference of the clients for a screening technology per age group. An independent samples t-test show that the difference in the preference for a screening technology between clients under 50 and clients over 50 is not significant (t=0,989).



Figure 12: client preference per age group

3.3.1. Non-adherent clients

The final subgroup analysis that is performed is the difference in the assessment of AHP criteria between the clients who do adhere to the screening and to those who do not. 6 clients are included in the group of nonadherent clients. Those clients have attended to none or less than half of the invitations to adhere in the population screening. The AHP outcome is exactly the same as the outcome of the entire population of clients in table 7. The difference between the non-adherent clients and the clients who do adhere in the population screening lies in the validating question. It shows that for 3 of the non adherent clients (50%) comfort is the most important reason the adhere to the population screening. The other 3 clients (50%) find the effectiveness of the screening the most important reason to adhere to the population screening. An ANOVA test shows that the opinion of this group does not significantly differ with the clients who do adhere in the population screening (P= 0,764). Table 10 shows the intention to adhere among the non-adherent clients per screening technology. It shows that there is uncertainty in this group whether to adhere to the population screening or not. 1 client (16,7%) will definitely adhere in a screening with digital mammography, no clients will definitely adhere in a screening with PAM3. 2 clients (33,3%) are not sure whether to adhere to a screening with digital mammography versus 3 clients (50%) in a screening with PAM3. 2 (33,3%) clients will probably not adhere in a screening where digital mammography is used versus 1 client (16,7%) when PAM3 is used. Based on this table it cannot be concluded if PAM3 would lead to a higher adherence in this group of clients.

	Digital mammography		PAM3		
Intention to adhere?	Frequency	Percent	Frequency	Percent	
Definitely yes	1	16,7%	0	0%	
Probably yes	1	16,7%	2	33,3%	
I am not sure	2	33,3%	3	50%	
Probably not	2	33,3%	1	16,7%	
Definitely not	0	0%	0	0%	
Total	6	100%	6	100%	

Table 10: intention to adhere to the population screening per screening technology among non-adherent clients



Figure 13: preference per subgroup

3.2. Patient centered decision making

Both professionals as clients are asked how they value the clients' opinion in the choice for a screening technology (table 12). A majority of the clients find their opinion important (38%) to very important (44%). 15% of the clients are neutral about their role in the choice for a screening technology and only 2% find their opinion very unimportant. The professionals are more divided in their opinion. 32% of the professionals find the client's opinion in the choice for a screening technology important, and 32% find the clients opinion very important. 11% of the professionals are neutral about the client's opinion and 27% of the professionals find the client's opinion unimportant to very unimportant. An independent Kruskal-Wallis test shows a significant difference in this opinion (p=0,044).

How important is the clients' opinion in choosing a screening technology?					
	Professionals	Clients			
Very unimportant	16%	2%			
Unimportant	11%	0%			
Neutral	11%	15%			
Important	32%	38%			
Very important	32%	44%			

Table 12: importance of the client's opinion

The professionals are asked why they made that decision. The professionals who valued the client's opinion as important to very important answered that the client has the main priority in the population screening since it is voluntarily. If the technology is not effective enough or not comfortable enough, the adherence rate will drop, thus the population screening will miss its goal, namely; the prevention of breast cancer. The professionals who find the client's opinion unimportant to very unimportant answered that clients only judge the comfort of the screening technology. The client has too little knowledge of the effectiveness of the screening technology to make a decent judgment.

Both professionals as clients are asked what opinion they find most important in the choice for a screening technology in population screening. 31% of the professionals find the opinion of the radiologist the most important. The RIVM and LRCB share a second place, 24% of the professionals find their opinion most important (figure 14).



Figure 14: most important opinion in the choice for a screening technology, professionals

The clients are asked what opinion is most important in the choice for a screening technology as well. This question is simplified since the client does not know the precise tasks of the RIVM, LRCB and LETB. These three organizations are summarized under 'government & advisory bodies' (figure 15). 47% of the clients find the opinion of the radiologists most important, followed by their own opinion (30%). The opinion of both managers (2%) as the government and advisory bodies (3%) are valued as the least important.



Figure 15: most important opinion for clients in the choice for a screening technology

4. Conclusion

The AHP results show that PAM is preferred over digital mammography by both professionals as clients if it performs with a sensitivity of 85% and a specificity of 90%. The effectiveness is the most important criterion in the choice for a screening technology in population based screening. Before PAM is acceptable as a screening method, it should perform at least as good as digital mammography, not only on effectiveness, but also on efficiency. There is no change in the intention to attend if PAM is used instead of digital mammography if their performance is equal. Although the clients' opinion is important in the adherence to the population screening, the opinion of the radiologist is valued as the most important one. PAM could be a suitable screening technology in the future for clients with dense breasts.

The intention to adhere to the screening is not dependent on the technology that is used. Clients will adhere in the population screening for breast cancer, no matter whether digital mammography or PAM3 is used.

There is a difference in the opinions between the professionals and the clients about patient centered decision making. The professionals prefer a passive role for the client, when the client would rather prefer a collaborative role in medical technology assessment.

5. Discussion

The discussion will address some of the findings of this study. The first paragraph is about the findings on the preference of the clients in the study. Second, the findings on the preference of the health care professionals will be addressed, and the discussion will end with some remarks on the interview methods used in this study.

5.1. Clients

There are differences measured in the preference a screening technology between the AHP and the closed ended questions. The AHP shows a preference for PAM3 over digital mammography. After the AHP was filled in, closed questions needed to validate the answers the clients had given in the AHP. The clients valued 'effectiveness' as the most important reason to adhere in the population screening. This is in line with the AHP outcome. The 'risks' of the screening are still valued as the second most important criterion to attend to the population screening, although the values of 'risks' and 'comfort' are closer to each other than in the AHP outcome. Another surprising outcome is the calculation of the Spearman correlation between the ranks that are assigned in the AHP and in the closes ended question. One would expect that the ranks assigned in the AHP are related to the ranks assigned in the closed ended question. Spearman's Rho shows that there is no relationship between the two different ranks though. There is no easy explanation that can be found for this outcome.

There is also a difference in the intention to adhere to the screening between the AHP outcome and the closed ended question. Since the AHP outcome shows a preference for PAM3, one would expect that the intention to adhere is also higher for PAM3 than it is for digital mammography. Although the intention to adhere remains high for both digital mammography (85,2%) as PAM3 (84,5%), there is more uncertainty among the clients whether they will adhere in a population screening with PAM3. Less clients answered that they will definitely adhere in a screening with PAM3 than in a screening with digital mammography. The number of clients that will probably adhere in a screening with PAM3 is higher than the number of clients that will probably adhere in a screening with digital mammography. Although the data analysis shows that this difference between digital mammography and PAM3 is not significant, it shows that there is uncertainty among the clients whether they will truly prefer PAM3 above digital mammography as a screening method. It was expected that the adherence to the population based screening could increase by implementing a more comfortable, client friendly method. The results section on the non-adherent clients also shows that there is no decisive answer whether this adherence would increase. All clients answered that they either probably will adhere to the screening, that they are not sure yet, and that they probably will not adhere to the screening. Since none of the clients answered that they definitely will or will not adhere to the screening, this only shows the uncertainty among this group of clients and the intention to adhere. When PAM is in a later stage of development, new research needs to be performed to measure the preference for a screening method when there is clarity about the effectiveness of the screening technology.

One of the clients answered that she will definitely not adhere to a screening where PAM3 is used since it is a waste of money in her opinion. The AHP score of this clients shows that this client favors PAM3 over digital mammography though. A possible explanation could be that the client took the efficiency of the screening technology in account in the validating question, a criterion that was only added in the AHP for the professionals.

In the interviews with the professionals, it became clear that many clients complain about the discomfort of the digital mammography. It was expected that the criterion 'comfort' would be valued as important in both the AHP as the validating questions. This expectation especially arose in the group of non- adherent clients, since 14% of this group does not adhere to the screening due to discomfort [30]. As mentioned above, the comfort of the screening technology is valued as the least important in the AHP. The closed ended question shows that 50% of the non-adherent clients find 'comfort' the most important reason to adhere in the population screening though. This is contradictory with the AHP outcome where only one of these clients

values 'comfort' as the most important criterion. 4 out of these 6 clients find all three criteria just as important in the AHP, and 1 client values 'risks' as most important AHP criterion. It shows that the group of 4 nonadherent clients assesses a higher value to 'comfort' but not at the expense of the other two criteria.

The number of non-adherent clients (N=6), 2,8% of the clients in the study are non-adherent to the population screening. This is a too small number to generalize this outcome to the entire population of non-adherent clients. If the study could have reached more of the non-adherent clients, the comfort of the screening technology would perhaps be valued with a higher score in both AHP as validating questions. Since comfort is important to this group of clients in the closed ended question, PAM could possible a suitable replacement for this group of non-adherent clients.

5.1.1. N of clients.

It was expected that around 600 clients would fill in the questionnaire completely. At the closure of the questionnaire, 850 respondents have viewed the questionnaire. 684 of these respondents pressed the 'complete questionnaire' button. Many of these respondents skipped questions or were treated for breast cancer. These respondents are excluded from the study. Therefore, only 208 of the questionnaires were useful to be tested for inconsistency. After testing, 142 respondents were left to be added in the study. This is not the number respondents aimed for. Despite this low number of respondents, the level of inconsistency is low, 68,3% of the respondents that were left could be included in the study. Mulder conducted a preference study for client preference in preventive health trough AHP as well, only in colorectal screening [7]. Here, 169 of the 1200 respondents (=14,1%) were consistent enough to be added in the study. The main problem here was that the respondents find it difficult to assess sensitivity and specificity. In this study, some people still find it difficult to fill in these questions, though the level of inconsistency shows that this problem is somewhat overcome.

5.2. Health care professionals

The professionals valued 'effectiveness' as the most important criterion for a screening technology in population based screening. This is as expected at the beginning of this study because all technology in health care should be effective before it could be implemented. The efficiency of the screening technology is valued as second most important, only with a low value of 0,151. Since the population screening is funded by the Dutch government, it is important for a screening technology to be as efficient as possible. For PAM3, this is not the case yet since the scan time is three times as high as digital mammography. Normally, 65 to 70 clients are screened in one bus daily. With PAM, 20 to 23 clients can be screened on a daily base. It will not be attainable then to screen the entire target population unless a second bus will be used which also means that more personnel are needed. Also, the opening hours of the bus need to expand, and the bus will be in one place for a longer period of time. This is another increase in the costs associated with the population screening. The costs will then increase to such an extent that the population screening is not cost-effective anymore. This could result in a dispense of the population screening by the Dutch government. The low valuation of the efficiency could be due to the population included in the study. If all stakeholder groups described by Wallner were included such as the Dutch government, the efficiency of the technology would be valued as more important [8]. Unfortunately, these stakeholders could not be included in the study.

When this study is compared with the study of Hilgerink, it shows the difference in importance of the different criteria between use of technology in the population based screening and in diagnostic screening [5]. Although in this study the efficiency of the technology did not receive a high AHP value, it is still in second place. The study of Hilgerink shows that effectiveness is the most important criterion, just as in this study. The risks of the technology takes a second place though, followed by efficiency, and finally comfort. This comparison shows that in the population screening the efficiency is more important than in diagnostic screening which is in line with the expectations. In this study, comfort is more important than in the study performed by Hilgerink. The

professionals explained this since the adherence to the screening is still somewhat dependent on the comfort of the technology. Some clients do not adhere to the screening due to discomfort.

The importance of the tumor characteristics is also assessed by Haakma [4]. Here, the most important tumor characteristics are: 1)the mass margins, 2)the mass shape, and 3)the vascularization. This top 3 is different from the importance of the visualization of the tumor characteristics in this study where: 1)Mass margins, 2)micro-calcifications and 3)mass shape are valued as most important. The micro-calcifications are not added in the study by Haakma. This shows the difference between the assessment of screening technology in the population screening and hospital care as well. The visualization of micro-calcifications is an important factor in the population screening, since its presence can make the distinction between benign and malignant tissue. If this cannot be visualized with PAM, this will lead to uncertainty in the diagnosis of the mass that is found in the breast. Consequently, the client needs to be referred to the hospital for further research more often. The population screening. This damage could then result in a lower adherence to the population screening.

The radiology assistants believe that the ergonomics for the client lowers the adherence to the population screening. They believe that the table is not suitable to be used in the population of clients. Elderly clients develop several physical problems, e.g. back problems, breathing problems, obesity, or loss of mobility. These problems make the screening difficult for the client. First because it could be difficult to climb on the table, and second to lie in prone position for a period of at least 15 minutes. The radiology assistants responded that this would increase their workload as well, since they have to aid the client to climb on the table and position her in the right way. The table is also not suitable for wheelchair dependent clients, they will be forced to exclude themselves from the population screening. So the current situation shows that PAM could be an adjunction to the screening with digital mammography, but not a replacement.

5.2.1. Health care professionals on patient centered decision making.

The clients are uniform on their role in the population screening. They find their opinion very important, together with the opinion of the radiologist. This fits the description of the client in the collaborative role very well. The health care professionals do not fully agree with the clients. This is based on both closed ended questions as the opinion of the health care professional why they find the clients opinion important or not. The health care professional values the opinion of the clients to a certain extent. The opinion of the clients is valued as an important one in topics such as the improvement of comfort during the screening. The health care professionals believe that a more comfortable screening technology will lead to higher adherence, which is the goal of the population screening. The clients' opinion is already taken into account by performing studies to make the digital mammography more comfortable. According to the health care professionals, the client should only judge the comfort of the device. In their opinion the client has not enough knowledge about the effectiveness, risks, and efficiency to make a proper judgment about the implementation of the screening technology. This tasks should remain for the health care professionals only. So from this point of view, the health care professional does value the clients opinion to a certain extent, but the role of the client cannot go any further than somewhere between passive and collaborative.

5.3. Interview methods

Different methods are used to collect the data from the professionals and the clients. The professionals are interviewed face to face. This is done because the professionals needed a more extensive explanation about PAM to make a proper judgment about the technology and to offer the possibility to ask questions about the technology as well. The clients filled in a web based questionnaire. The face to face interviews have lead to more insight in how the patient centered decision making is valued. The large sample of respondents unfortunately made it impossible to do face to face interviews. Face to face interviews would make the sample less inconsistent but also smaller and therefore less representative for the population. These different interview methods could have influenced the results of the study.

6. Recommendations

Recommendations for the development of PAM:

- The scan time should be shorter. A scan time of around 5 minutes for two breasts to advisable. If this scan time is unattainable for PAM to achieve, it will probably not be cost-effective to implement PAM in the population screening.
- The table needs ergonomic adjustments to keep working with PAM comfortable for both the clients as the people who work with the technology. The table should be adjustable in height for clients to climb on and health care professionals to work under the table. Some of the health care professionals commented that it might be an idea to tilt the table so the client can sit or stand. Many clients in the population screening are old, overweight, or have back problems. Therefore, they cannot lie or are they even able to climb in this position.
- The effectiveness of PAM should be minimally as good as digital mammography. Therefore, it could be a more useful technology for younger clients, where the effectiveness of digital mammography is only low.
- Focus on the imaging of the different tumor characteristics, especially the micro-calcifications.

Recommendations for patient centered decision making in preventive health care:

• Focus on the opinion of the client on the comfort of the screening and how this could be increased.

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Appendix 1: Organization of the population based screening for breast cancer

Around 1.1 million women of the target population are invited to participate in the screening. These women are invited based on data from the municipal administration. Women who are already familiar with breast cancer are excluded from participation in the screening. These women have a tailored follow up scheme. The invitations are sent automatically and contain the date, location and time when the screening will take place. In addition, a leaflet is added which describes what the value of screening is and how it will be executed. If the woman does not respond to the invitation, a reminder is sent within a few weeks. The screening is carried out in one of the mobile screening centers and is performed by a radiology assistant (figure 16). The radiology assistant takes a look at the mammograms, mainly to judge the quality of the image and to mark possible abnormalities. If the breasts are hard to judge (BI-RADS 0) further research is needed through MRI or ultrasound. The woman is then referred to the local breast policlinic. All other breast images are send to the radiology department where the images are read independently by two radiologists. This so called 'double reading' is done to decrease inter-observer variability and leads to more detected cancers [46].

After the mammograms are taken all women receive a letter with the outcome of the screening within two weeks. When the BI-RADS score is category is 4 or 5, the general practitioner (GP) of the woman is contacted first. The GP then contacts the woman about the outcome of the screening and further steps that needs to be taken. Mostly, the woman is send to the breast policlinic of the local hospital. The woman also receives this information in a letter which includes the outcome and a leaflet containing information on further actions that need to be taken.

Women who have a BI-RADS score of 1-3 only receive a letter. In this letter is emphasized that the screening does not prevent the woman from getting interval breast cancers. If a woman gets any complaints, she is advised not to wait for the next screening but to attend to her GP.



Figure 16: schematic image of the screening bus

Appendix 2: AHP criteria

Definition of the criteria used in the AHP.

1. Efficiency

All the sub-criteria that require a certain input of time, finance, or personnel are labeled as efficiency.

- 1.1. *Man power*: All the personnel that are needed to perform the scan and guide the patient right before, during, and after the scan takes place.
- 1.2. Price(Purchase, maintenance & refractory life): The amount of money needed to purchase the screening device. This requires all the equipment to be able to fully perform the screening and read the outcome. Also includes the amount of money needed for regular maintenance, regular check-ups and repairs on the device. Finally, the preservability of the device, ea. after what time the device needs to be replaced completely with a new one.
- 1.3. *Scan time:* The time it takes for the patient to fully undergo the screening. This time includes the preparation the woman need before the screening can be performed, as well as the time needed to switch the device to screen the other breast.
- 1.4. *Ergonomics*: Factors in- or decreasing the physical workload and ease of use.

2. Effectiveness

The effectiveness of the devices is described by their sensitivity and specificity [25]. For these two items, three scenarios are created (1) a worst case, (2) an average case, and (3) a best case scenario.

- 2.1. *Sensitivity*: The sensitivity is valued as the probability the outcome of the breast screening is a true positive. The outcome is a value rated between the 0 and 100%. [47]
- 2.2. *Specificity*: The specificity is valued as the probability the outcome of the breast screening is a true negative. The outcome is a value rated between the 0 and 100%.

3. Client comfort:

The amount of comfort related to the screening devices.

- 3.1. *Comfort:* Measured as the amount of pressure needed to adequately perform the scan presented in Newton associated with the level of pain the woman experiences.
- 3.2. Posture & ergonomics: The position the woman is placed in during the screening. This could be standing up straight, sitting or lying down. Ergonomic factors in- or decreasing the physical load for the clients are taken into account.

4. Risks:

The risks involved with the screening technology for both the client as the radiology assistant.

4.1. *Radiation and protective measures*: The level of radiation that the screening technology produces and the protection that is needed.

<u> </u>		<u> </u>	81		
Criteria	Subcriteria	Digital mammography	Photoacoustic mammoscope		
1. Efficiency	1.1 Man power	1 digital mammography radiology assistant (female)	1 radiology assistant possibly assisted by 1 technical worker Purchase price €400.000 Annual maintenance €10.000		
	1.2 Costs (purchase- and maintenance	Purchase price: €500.000 Annual maintenance: €40.000 Refractory life: 10 years			
	1.3 Scan time & read off time	Scan time: 5 minutes per patient.	Scan time: 10 to 15 minutes per patient (this will be shorter in the future)		
	1.4 Ergonomics	Adjustable device. The table can be adjusted by pressing the buttons with the foot; precise adjusting of the breast happens by hand.	Unadjustable device. To adjust the breast, the worker needs to climb under the table and adjust the device by hand.		
2. Effectiveness	2.1 Sensitivity	Digital mammography has a sensitivity of 85.5%	Possible sensitivity values for PAM are Scenario 1:50% Scenario 2:70% Scenario 3:85%		
	2.2 Specificity	Digital mammography has a specificity of 92%	Possible specificity values for PAM are: Scenario 1: 45% Scenario 2: 75% Scenario 3: 90%		
3. Comfort:	3.1 Comfort	The breasts are compressed with a pressure of 120N to 200N (12- to 20 kilograms). Of all women, 70% experience a certain level of discomfort/pain due to the compression. 2 out of 3 women experience little to moderate pain, 1 out of 3 women experience moderate to severe pain. In this group the average pain score is measured by a VAS score of 7 out of 10.	The breast are slightly compressed between a glass plate and the screening laser. The breasts are more or less compressed based on the patients' sense. Since the breasts are barely compressed, the woman will experience little or no pain.		
	3.2 Posture & ergonomics	The woman stands with one breast at the time compressed in the mammograph.	The woman lies in prone position . The table is not adjustable (yet) clients need to climb on it with steps.		
4. Risks	4.1 Radiation	There is a certain amount of x-ray radiation involved in the screening. 86 out of 100.000 women develop radiation related cancers within 20-30 years and 10-14 women out of 100.000 die of these radiation related cancers.	There is no radiation involved, only a laser beam and an ultrasound wave. These do not affect the woman's health. Both radiology assistant and client need to wear protective goggles. The laser light could damage the eye when it is not protected.		

Appendix 3: Performance matrix

Appendix 4: AHP client hierarchy

The clients received a simplified version of the AHP hierarchy. The criterion 'efficiency' is excluded from the hierarchy (figure 17).



Figure 17: AHP hierarchy adjusted to the clients

Appendix 5: Modeling uncertainty: expected performance of PAM

Two studies have been used to create scenarios for the expected performance of PAM. Hilgerink created scenarios for the performance of PAM based on the opinions of early adopters of PAM and the creators of the technology [5]. The performance of PAM is compared with digital mammography combined with ultrasound, MRI, and digital mammography combined with PAM. A Markov model is used to convert the weighted AHP values into assumed performance values (figure 18). Both sensitivity and specificity are calculated with the formula: $pnorm(ln(1/(1-x) - 1))^{n}(ln c / ln 0, 5)$



Figure 18: AHP values shifted into values for sensitivity and specificity

Table shows the results of the AHP values converted into sensitivity and specificity values. The scenarios for PAM vs. MRI are much more positive than the values for PAM versus digital mammography & ultrasound, and digital mammography & PAM.

	Worst	Average	Best
AHP values for PAM vs. MRI	AHP= 0,342	AHP= 0,479	AHP= 0,709
Sensitivity	0,744	0,847	0,956
Specificity	0,661	0,793	0,939
AHP values for PAM vs. MMG+US/MMG+PAM	AHP= 0,25	AHP= 0,302	AHP= 0,333
Sensitivity	0,637	0,696	0,727
Specificity	0,685	0,738	0,765

Table 13: AHP values shifted into three scenarios; worst, average and best

Haakma created several performance scenario's for PAM based on the principal of expert elicitation. A group of 18 radiologists specialized in reading mammograms were asked to make assumptions on the performance of PAM. The group was divided in early adopters and majority. Furthermore an overall scenario with the opinion of the entire expert group is created. This lead to concrete data on the expected performance on diagnostic accuracy of PAM (table 2).

	Early adopters			Majority			Overall		
	Lower	Mode	Upper	Lower	Mode	Upper	Lower	Mode	Upper
Sensitivity	67.7%	81.7%	91.9%	51.2%	67.4%	74.3%	58.9%	75.6%	85.1%
Specificity	70.2%	79.1%	88.4%	40.8%	58.5%	70.7%	52.2%	66.5%	77.6%

 Table 14: scenario's on the performance of PAM derived from 'Haakma' [4]

Appendix 6: Interview questions professionals (Dutch)

- 1. In het AHP zijn verschillende criteria besproken. Zijn er nog andere criteria die u van belang vindt in de keuze voor een screeningsmethode?
 - a. Ja, namelijk
 - b. Nee.
- 2. Voor bepaalde subgroepen binnen het bevolkingsonderzoek brengt digitale mammografie het borstweefsel minder goed in kaart. Voor welke groepen zou u het gebruik een van andere screeningstechnologie in overweging willen nemen?
 - a. Algemene populatie vrouwen van 50 to 75 jaar:
 - b. Populatie vrouwen met een hoge dichtheid (dens)van het borstweefsel:
 - c. Populatie vrouwen met verhoogd risico op borstkanker:
 - d. Anders namelijk:
- 3. .Zou PAM overwegen boven mammografie wanneer de effectiviteit van PAM uitkomt op:
 - a. Een sensitiviteit van 85% en een specificiteit van 90%?
 - i. Ja
 - ii. Nee
 - b. Een sensitiviteit van 70% en een specificiteit van 75%?
 - i. Ja
 - ii. Nee
 - c. Een sensitiviteit van 50% en een specificiteit van 45%?
 - i. Ja
 - ii. Nee
- 4. Radiologen: Mammografie en PAM kunnen een mogelijke tumor/massa lokaliseren door het in beeld brengen van verschillende karakteristieken. Hoe belangrijk vindt u de volgende karakteristieken op een schaal van 1 tot 10? De eerste 6 karakteristieken worden door zowel mammografie als PAM in beeld gebracht. Doordat PAM de vascularisatie rondom een massa in beeld kan brengen, biedt dit als extra mogelijkheden het in beeld brengen van de zuurstofsaturatie van de bloedvaten rond een mogelijke massa en de stijdheid en dichtheid van de massa.
 - a. Randen massa
 - b. Vorm massa
 - c. Grootte van massa
 - d. Vascularizatie
 - e. Locatie massa
 - f. Micro-calcificaties
 - g. Zuurstofsaturatie
 - h. Stijfheid en dichtheid van massa
- 5. Hoe belangrijk vindt u de mening van de cliënt in de keuze voor een screeningstechnologie?
 - a. Geheel onbelangrijk
 - b. Onbelangrijk
 - c. Neutraal
 - d. Belangrijk
 - e. Zeer belangrijk
- 6. Waarom vindt u dit?

- 7. Wanneer de cliënten een andere voorkeur hebben voor een screeningsprogramma heeft dan u, in hoeverre beïnvloedt dit uw voorkeur?
 - a. Nooit
 - b. Meestal niet
 - c. Neutraal
 - d. Meestal, wanneer de cliënt goede argumenten heeft.
 - e. Altijd
- 8. Welke mening vindt u het belangrijkst in de keuze voor een screeningsmethode in een landelijk programma?
 - a. RIVM
 - b. Screeningsmanager
 - c. LETB
 - d. LRCB
 - e. Radiologen
 - f. Radiologie laboranten
 - g. Cliënten
 - h. Anders namelijk:
- 9. Verwacht u bij het gebruik van PAM een verandering in de werktevredenheid?
 - a. Ja omdat:
 - b. Nee omdat:

Appendix 7: Interview questions clients (Dutch)

- 1. Leeftijd:
- 2. Hoogst genoten opleiding:
 - a. Lager onderwijs
 - b. Middelbaar onderwijs
 - c. MBO
 - d. HBO (HTS, HEAO, Bachelor)
 - e. WO (Universitair onderwijs, doctoraalopleiding, TH, Master)
- 3. Hoe vaak heeft u gehoor gegeven aan de oproep om deel te nemen aan het bevolkingsonderzoek voor borstkanker?
 - a. Aan alle oproepen
 - b. Aan meer dan de helft van de oproepen
 - c. Aan minder dan de helft van de oproepen
 - d. Aan geen enkele oproep
 - e. Ik heb nog geen oproep ontvangen.
- 4. Bent u ooit behandeld voor borstkanker of wordt u op dit moment behandeld voor borstkanker?
- 5. Stel, de overheid nodigt u uit om deel te nemen aan de screening waarin gebruik wordt gemaakt van mammografie. Bent u dan van plan aan de screening deel te nemen?
 - a. Beslist niet
 - b. Waarschijnlijk niet
 - c. Mischien wel/misscien niet
 - d. Waarschijnlijk wel
 - e. Beslist wel
- 6. Stel, de overheid nodigt u uit om deel te nemen aan de screening waarin gebruik wordt gemaakt van PAM. Bent u dan van plan aan de screening deel te nemen?
 - a. Beslist niet
 - b. Waarschijnlijk niet
 - c. Mischien wel/misscien niet
 - d. Waarschijnlijk wel
 - e. Beslist wel
- 7. Wat bepaalt voor het grootste deel uw keuze om wel of niet deel te nemen aan het bevolkingsonderzoek?
 - a. Effectiviteit
 - b. Comfort
 - c. Risico's
 - d. Anders namelijk:
- 8. Hoe belangrijk vindt u het dat uw mening door de overheid wordt meegenomen in de keuze voor een screeningsapparaat?
 - a. Geheel onbelangrijk
 - b. Onbelangrijk
 - c. Neutraal
 - d. Belangrijk

- e. Zeer belangrijk
- 9. De mening van professionals (radiologen, laboranten, overheid) in mijn keuze om wel of niet deel te nemen aan het bevolkingsonderzoek is voor mij:
 - a. Geheel onbelangrijk
 - b. Onbelangrijk
 - c. Neutraal
 - d. Belangrijk
 - e. Zeer belangrijk
- 10. Welke mening vindt u het belangrijkst in de keuze voor een screeningsmethode?
 - a. Managers van het bevolkingsonderzoek
 - b. Overheids- en adviesinstanties
 - c. Radiologen
 - d. Radiologie laboranten
 - e. Uw eigen mening
 - f. Anders namelijk:

Appendix 8: Difference in preference of professionals per region

The preference for screening technology are assessed per region within the population screening of 'Bevolkingsonderzoek Oost'. It shows that the health care professional in the regions of Nijmegen and Enschede have a slight preference for digital mammography. The health care professionals in the region of Apeldoorn have a large preference for PAM3. This table shows that due to the large preference for PAM3 in the region of Apeldoorn, the overall preference for PAM3 is higher than for digital mammography.



Figure 19: preference of the health care professionals per region

Appendix 9: Shift in preference; effectiveness scenarios

The images below show the shifts in preference for a screening technology when the effectiveness of PAM increases. The green lines present the shift in preference, that is, when the preference for digital mammography and PAM are equal. The AHP value is then 0,5. Both figure 20 and 21 show that the effectiveness of PAM (or any other screening technology) should at least equal the effectiveness of digital mammography before it could be accepted in the population screening.



Figure 20: sensitivity scenarios and preference for PAM or digital mammography.



Figure 21: specificity scenarios and preference for PAM or digital mammography.