Breast Reconstruction Surgery in the Netherlands, an Alternative Payment Method for Breast Reconstruction Surgery. Are Extra Fees Feasible in the Context of Reconstructive Surgery?

Saeed Saad Alqahtani, Mohammed Ahmedhane Kilani, and Shahbaz Mansoor

Abstract—Breast cancer is the most common cancer in women in the Netherlands, and breast reconstruction is becoming a common surgical procedure for women who have had a mastectomy. Reconstruction post breast cancer treatment is covered by conditional reimbursement until 01-04-2020 as long as it is an autologous fat transplant. Conditional reimbursements are special legal exceptions under constant consideration by the Ministry of Health and require evidence on treatment and cost effectiveness to be moved to basic healthcare package.

Surgeons at Maastricht UMC+ have developed sophisticated techniques for women that undergo a reconstruction surgery to recover sensitivity of the breasts. Improved sensitization would lead to a better quality of life and protect the skin against thermal and mechanical injuries. However, current health insurance coverage of breast reconstruction does not permit these additions. Furthermore, the reimbursement system in The Netherlands does not allow people to pay an extra fee for these additions.

Index Terms— Breast reconstruction, Reimbursement system, Public Health Insurance, Netherlands.

I. INTRODUCTION

1.1 Breast reconstruction surgery in the Netherlands

Approximately 14,000 women are diagnosed with invasive breast cancer each year in the Netherlands, and about 1,900 have an in-situ carcinoma. A woman's risk of having breast cancer over the course of her life is 12-13%. This means that breast cancer is the most common form of cancer in women in the Netherlands (1). Breast reconstruction is increasingly becoming a more common surgical procedure for women who have had a mastectomy. In the Netherlands, 14% of the plastic surgery is reconstructive surgery.

The preferred breast reconstruction technique is the deep inferior epigastric artery perforator flap (DIEP) for which autologous tissue is used to gain a more natural and permanent result with high patient satisfaction (2). However, this technique is not possible in patients with previous abdominoplasty, lack of sufficient subcutaneous fat or scarring in the abdominal region (3). In that case, the buttock/thigh flap is the donor site of choice (4). Whether or not the patient receives radiation therapy after the mastectomy will determine the possibility of having an

immediate breast reconstruction during the same operation as the mastectomy. Immediate autologous breast reconstructions show better results in aesthetics, cost-efficiency, and psychological well-being. Operative times between immediate and delayed bilateral breast reconstructions do not differ significantly with 456 and 467 minutes, respectively. Despite the clear benefits, the number of immediate autologous breast reconstructions is highly variable among institutions (2). While no statistically significant differences in complications can be identified, the immediate reconstruction does have lower percentages of major complications and total or partial flap loss.

1.2 Recent developments/innovations in breast reconstruction

Microsurgical nerve coaptation of the sensory nerve of the DIEP flap to the 2nd and 3rd intercostal nerve is a method to improve sensitization of the reconstructed breast (5). This technique leads to an increased operating time by 15-30 minutes on average per breast, with no increased risk of complications (6). Considering the operative time of 456 minutes, nerve coaptation will only extend operative time by 6.6-13.2% (5, 6).

Improved sensitization will lead to a better quality of life and protect the skin against thermal and mechanical injuries. This sensory recovery is measurable after 6 months counting from the surgery, while for non-innervated breasts this will take 12 months. In addition, the sensory recovery in innervated breasts gradually improves over time with a higher chance of approaching normal sensation values. Overall, three factors are hypothesized to determine the

amount of sensation that can be restored. The quality of the recipient nerve is an important factor, which can be worsened by radiotherapy. The quality and type of nerve anastomosis, which is the connection between nerves. Lastly, the quality of preoperative sensation of the donor site skin can contribute to the potential to restore sensation by this procedure. (5, 7).

1.3 Quality of life after breast reconstructive surgery

Historically, the concept of health has been associated with the physical aspect of well-being. However, in recent years there has been an acceptance of a broader definition of health

Published on February 16, 2020.

Saeed Saad Alqahtani, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands.

(email: s.alqahtani@student.maastrichtuniversity.nl)

Mohammed Ahmedhane Kilani, Saudi Center for Disease Prevention and Control, Riyadh, Saudi Arabia.

Shahbaz Mansoor, Maastricht University, Maastricht, The Netherlands and Department of General Surgery at Midland Regional Hospital Mullingar, Mullingar, Ireland.

and well-being that includes the mental and psychological side of the concept. There are several studies about the psychological impact of breast reconstruction after a mastectomy in cancer patients, most of them reinforcing the idea of the importance of reconstructive surgery for the mental and sexual well-being of women, as well as for the quality of life of the patients.

For example, a study by Stevens et al. (1984) suggests that there is a lower incidence of psychological morbidity after immediate breast reconstructions, and breast reconstruction should be offered as an alternative for women with early breast cancer (8). Similarly, Edström Elder, Brandberg, Björklund, Rylander, Lagergren, Jurell, Wickman and Sandelin (2005) after their study concluded that "Most women were satisfied with immediate reconstruction, and the major determinant of aesthetic satisfaction was completion of the procedure. Although many factors may influence quality of life, one year after breast cancer surgery with immediate reconstruction scores are equivalent to those of the normal population" (9). More recently, Cornelissen et al. (2017) in a pilot study, concluded that "improved sensation in the autologous reconstructed breast, with the addition of microsurgical nerve coaptation, has a statistically significant positive impact on the quality of life in breast cancer survivors" (10).

These conclusions support the premise that the importance of breast reconstructive surgery transcends the physical or aesthetical aspect of it. It is also crucial for the patients' quality of life, which includes self-esteem, mental, psychological and sexual health.

1.4 The reimbursement system in the Netherlands

The healthcare providers (such as hospitals) are independent organizations and most provide care on a non-profit basis. This contrasts with individual care providers that operate on a for profit basis. There are teaching and general hospitals. Typically, at a teaching hospital (such as a University Medical Centre), the governance includes an executive board, supervisory board and representative councils. They can also be supported by many services and facilities for support in implementation of scientific research. The healthcare system of the Netherlands is private in nature. The noteworthy feature is that the national social health insurance is guaranteed by public law (AWBZ) while the system is built on private law that in turn provides guarantees under public law (ZvW) and supplementary private insurance.

There are 3 notable features of the Dutch Healthcare system:

1. Major medical risks: provided for by the Exceptional Medical Expenses Act (AWBZ). This can be considered as the 1st feature. This covers national insurance for long-term and unaffordable care.
2. Basic healthcare: provided pursuant to ZvW (Health Insurance Act). This can be considered as the 2nd feature. This covers obligatory insurance for essential curative care.
3. Less essential forms of care: covered by the supplementary health insurance. This can be considered as the supplementary feature. This covers voluntary insurance that varies in its range of coverage.

To understand how the reimbursement works under the

Dutch healthcare insurance system, it is important to note the legislation that lay down the framework. They are:

1. The Health Insurance Act (Zorgverzekeringswet/ZvW),
2. The Long-Term Care Act (Wet langdurige zorg),
3. The Social Support Act (Wet maatschappelijke ondersteuning) and
4. The Youth Act (Jeugdwet).

In addition to the above, there are several general laws in place (including the Competition Act/Mededingingswet) and many specific healthcare acts (e.g. the Care Institutions (Quality) Act). (11, 12, 13)

1.4.1 Public Health Insurance in the Netherlands

The legal basis for providing public health insurance is carved out in the Healthcare Insurance Act (Zorgverzekeringswet), the Healthcare Insurance Decree (Besluit zorgverzekering), and the Healthcare Insurance Regulations (Regeling zorgverzekering).

The Health Insurance Act (ZvW, which provides hospital care) and the Long-Term Care Act (which focuses on other types of care) account for the bulk of the healthcare budget available in the Netherlands. In implementing the Health Insurance Act, private health insurance companies play a key role in a system based on "regulated competition" in addition to meeting several specific public requirements. The 400 municipalities (approximately) in the Netherlands are primarily responsible for enforcing these two acts. The Dutch healthcare authority acts as an observer and ensures compliance of the healthcare actors (insurance providers, care providers) with the Health Insurance Act (ZvW) and Healthcare Market Regulation Act (Wmg). (11)

The central government is directly involved in implementing the Health Insurance Act and sets many public requirements which guarantee the social nature of the health insurance. It is a legal obligation for health insurers to accept everyone who applies for the insurance. The care insurer can decide if a qualified person or an institution can provide insured care. The insurer may provide insured care to the insured i.e. in-kind insurance) or reimburse cost incurred by the insured (reimbursement insurance). (11,13)

The government decides on the coverage (content and extent) provided by the basic healthcare insurance but this intervention is only in the public interest. All healthcare insurers offer the same standard package. This means that the insurers are free to set their own free premium. Everyone who is 18 years and over should have health insurance and pay the nominal premium. This is unrelated to an individual's income. This doesn't change irrespective of whether the insurer provides an in-kind or reimbursement against costs paid out of own pocket type of model. The only exception where a different nominal premium amount might be offered is group insurance package where a maximum of 10% discount can be offered. 'Care allowance' is also given to those eligible to partly fund the compulsory health insurance cost.

Entitlement to care allowance is decided based on the fulfilment of several conditions. This is mainly decided based on the income of an individual. The government still has an important role in health policy development and implementation. For example, via the budget for health and

the content of the basic benefit package, the government has a major influence on cost development in the healthcare sector. (14)

The figure provides an overview of the interaction between the Government, the observer and the actors of the Dutch Healthcare system: (16)

Source: Health systems in transition (2016)

Financially, the insured under The Healthcare act (ZvW) are affected in the following ways:

(14, 15)

1. Compulsory excess-mandatory for persons aged 18 and over. This doesn't apply to

GP, maternity, obstetric and dental care for persons aged under 18. A fixed amount of deductible of €385 (for the year 2018) - must be paid out of pocket.

2. Voluntary excess- optional for those over 18 and above. This is offered by the insurer in addition to the compulsory excess up to a maximum of €500 in exchange for a discount on the premium (Higher the voluntary excess, lower the premium).

3. Out-of-pocket payment- insured foots a part of the bill. May happen when the insurance provider isn't in contract with a care provider or also when the insured pay for certain medicines, medical devices, seated patient transport and maternity care. This is not considered when calculating personal excess.

There are 2 types of Dutch Health Insurances: Compulsory basic insurance & Optional additional coverage. On top of the basic compulsory health insurance, the supplementary insurance plans are left to be determined by the insurance providers and the government has no say in this. It is also up to the insurance providers to enrol persons on to the plan.

Contents of basic and supplementary insurance packages (17, 18)

The following constitute the content of the basic health insurance package:

1. Medical care- provided by GPs, medical specialists, clinical psychologists and midwives.
2. Dyslexia care
3. Paramedical care
4. Oral care
5. Pharmaceutical care
6. Medical devices
7. Accommodation
8. Maternity care
9. Transportation of patients

For some treatments, there are exclusions from the basic insurance package:

1. For allied healthcare, generally, a maximum number of sessions are reimbursed;

2. Some elective procedures, for instance cosmetic plastic surgery without a medical indication, are excluded; and

3. In vitro fertilization: only the first three attempts are included.

The central government takes decisions on the content of the basic health insurance package, on cost-sharing, on tariffs for health services if not negotiable (based on advice from the Dutch Healthcare Authority) and on services that are not subject to free negotiations. The National Healthcare Institute advises the Minister on what services should be included in the package.

The main criteria for deciding the content of basic health insurance package refer to whether services are essential, effective, cost-effective and unaffordable for individuals. What constitutes "essential care" is arguable, and decisions can be hampered by a lack of information on the efficiency of a service. Other problems may arise about treatments of diseases resulting from unhealthy behaviour, or when pharmaceuticals covered by basic health insurance are used by other than the intended patient groups. In other words, if a treatment complies with established medical science and medical practice criterion, then it's expected that such a treatment will find its place under the basic healthcare package.

With regards to supplementary healthcare insurance package, it is an area for the insurers to provide additional packages to those that want additional coverage for dental care, physiotherapy, spectacles, birth control, additional reimbursements for medicines, comprehensive medical care outside the Netherlands and alternative medicine. The premium here can vary from €5-€50 and the basis for including a treatment under this package is to cover what is not covered by the basic healthcare insurance package. (14,15,17)

1.4.2 Conditional Reimbursement for plastic and reconstructive surgery

The content of basic statutory health insurance is laid down in the legal basis provided in Article 2.4 of the Health Insurance decree and Article 11 of the Health Insurance Act. The scope and content are partly determined by the state of science and practice and, if absent, by what is a responsible and adequate care and service in the field. (19)

Article 2.4 (b) of the Health Insurance decree lays down that treatment by plastic surgery is covered only if it is intended to correct according to the following conditions: "Treatment of plastic surgery is only covered if it is intended to correct:

1. Abnormalities in appearance that are associated with demonstrable physical functional disorders;

2. Mutilations resulting from a disease, accident or medical operation;

3. Paralyzed or weakened upper eyelids, if the paralysis or weakening results in a severe visual field limitation or is the consequence of a congenital defect or a chronic condition present at birth;

4. The following congenital malformations: lip, jaw and palate clefts, deformities of the bony face, benign proliferations of blood vessels, lymph vessels or connective tissue, birthmarks or malformations of urinary tract and genital organs;

5. Primary sexual characteristics in a determined transsexuality;" (20)

According to Dutch healthcare insurance policy Article 20, for plastic and/or reconstructive surgery, reimbursement costs of the surgical placement and surgical replacement of a breast prosthesis, other than after a complete or partial mastectomy, is not applicable. Only breast reduction, laser treatment and nose correction are examples of plastic surgery that come under insured care. The Assessment of Treatments involving Plastic Surgery (Werkwijzer beoordeling behandelingen van plastischchirurgische aard) is done by the Association of Physicians, Dentists and Pharmacists Working for Healthcare and Other Insurers (Vereniging van artsen, tandartsen en apothekers werkzaam bij (zorg)verzekeraars, VAGZ) Health Insurers of the Netherlands (Zorgverzekeraars Nederland, ZN) and the Health Care Insurance Board (College voor zorgverzekeringen, CVZ). (20)

From the foregoing discussion, it is evident that breast reconstruction surgery only if it falls under the conditions of plastic surgery. However, Article 2.2 (f) of the Health Insurance Decree states that the care included in Article 2.4 of the Health Insurance Regulations also includes until 01 April 2020 the following: "breast reconstruction after breast cancer with autologous fat transplant, insofar as the insured participates in research as referred to in the second paragraph, part a, to this care.". This constitutes the 'conditional reimbursement'. In other words, if a certain healthcare practice does not fall under established medical science and medical practice criterion, then it could be included under the conditional reimbursement section of the Healthcare insurance act and the related legislations. (18,20)

1.4.3 Procedure for acquiring insurance approval of reimbursement

The process of acquiring insurance approval of new medical techniques is explained with an example from the field of ophthalmology, regarding cataract surgery and the different lenses available to patients. Cataracts refers to a condition in which the lens of the eye becomes clouded, leading to blurry vision, muted colors, and light sensitivity. It may arise naturally with age, or from an illness or accident. The condition cannot reverse naturally, so surgery is required to replace the natural lens with an Intraocular lens (IOL). (21)

The standard IOL used for this surgery is a monofocal lens. The term monofocal indicates that the lens can only provide clear vision on one focal point (normally at a further distance) meaning glasses are still necessary for viewing something up close (22)

There are two other predominant types of IOLs that can be used for cataract surgery. In the multifocal lens, different areas of the lens have different focal points. Thus, vision at various distances is possible without the use of glasses. In the accommodating lens, special attachments push the lens forward when looking at something closely. Thus, although the lens has only one focal point, it can adjust, as in normal

healthy eyes, allowing vision at various distances as well. Generally, the accommodating lens provides somewhat less clear near

vision than in the multifocal lens, while the multifocal lens can cause a glare or more blurred distance vision ("Intraocular Lenses (IOLs): Including Premium, Toric and Aspheric Designs"; "Multifocal IOLs vs Monofocal and Accommodating IOLs"). (23)

In order to prove the necessity of health insurance coverage of these two additional lenses, two requirements of the College voor zorgverzekeringen (CVZ) – now Zorginstituut Nederland – had to be fulfilled:

1. It is healthcare that medical specialists aim to provide

2. The treatment is in accordance with the state of science and practice

The first indicates the healthcare professionals capable of administering these lenses, and whether this procedure falls under the accepted arsenal of care for that profession, determined by the care provider (24). Both lenses met these criteria, as ophthalmologists were specified as the healthcare professionals who can administer this treatment, and several eye clinics were found to already be doing so, with patients usually paying for the procedure themselves (21). The second requires that the treatment be effective and safe, as proven by sufficient research support (25).

The first attempt to appeal to the CVZ in 2008 was unsuccessful in proving that either of the two lenses met the state of science and practice: there were too many side effects for the multifocal lens and insufficient information on the effectiveness and side effects of the accommodating lens. Thus, it was necessary to collect more research support for the lenses and re-appeal in 2011. It was then proven that the side effects of the multifocal lens are quite small, and patients often still prefer them to the alternative option of wearing glasses with the monofocal lens. Thus, the multifocal lens now met the state of science and practice. The accommodating lens, on the other hand, was shown to pose a high risk of the original cataract symptoms returning. Thus, it still did not meet the status of science and practice. It was concluded that patients will only be reimbursed for the multifocal lens if it is truly medically necessary, such as in the case where glasses are not an option for the patient. Thus, insurance reimbursement is determined on a case-by-case basis. Patients who do not fall in the category of people for whom monofocal lenses with glasses is not an option will have to pay for the treatment of multifocal lenses themselves (21).

1.4.4 DBC/DOT system

A Diagnosis Treatment Combination (DBC), better known as a DBC healthcare product - is a 9-digit code that says something about the content of the total hospital activities (diagnosis, treatment and controls). In other words, the DBC provides information about the total treatment process. DBC healthcare products are used within specialist hospital care as well as mental health care (GGZ). The doctor or practitioner determines which DBC is issued. The rationale of the DBC system introduction in 2005 was that the focus of budgeting moved from position based (that is lump sum funding of the medical specialists and the providers) to remuneration based

on workload, hourly rate, and performance funding. Two systems were introduced for the decentralised Dutch healthcare - an A and B segment. An A-segment, with fixed national tariffs for health providers and medical specialists, is used for billing only. In the B-segment, provider prices are set based on local negotiations between provider and insurer, combined with fixed national tariffs for medical specialists. (26)

The government wanted to stimulate market forces in healthcare to a certain extent. The current DBC system offers opportunities, because:

- Hospitals and health insurers can negotiate with each other about the price and quality of care and treatments. The consumer can ultimately benefit from this.
- There is more transparency in the costs of certain treatments, allowing hospitals to optimize their operations and to continue to provide affordable and effective care.

A DBC contains all activities of a hospital and a medical specialist that are the result of a specific care request. This includes: (26)

- The diagnosis of a specialist
- Hospital treatments
- Follow-up checks (if applicable)

1.5 Increasing access to innovation

The surgeons at Maastricht UMC+ is an academic hospital have developed sophisticated techniques for women that undergo a reconstruction surgery to recover sensitivity of the breasts. The results are the best achievable both aesthetically and functionally, which implies a bigger investment of time and resources from the doctors as well as the patients. Furthermore, the waiting list for patients who want breast reconstruction with their own tissue in The Netherlands can exceed 2 years.

To shorten the waiting list and to have a more aesthetic result along with the reconstruction surgery, one solution could be that patients willing to pay a supplement could do so, as is possible almost everywhere in the world. However, the reimbursement system in The Netherlands does not allow people to pay an extra fee, neither for more aesthetic results in addition to reconstructive surgery, nor for a faster surgery.

The financial profit made from the supplement could partially be used to create extra capacity, hire more surgeons, and stimulate innovation and development in new processes to improve the reconstructive surgery, elements that often are not initially insured by national health care. Earlier introduction of evidence-based treatments may therefore also be of benefit for every patient. Finally, and most importantly, the money could be allocated to a fund for patients who are not able to pay for the additional service, resulting in a win/win situation.

Maastricht UMC+ needs a feasibility study that examines the ethical, political, economic and medical impact of the issues previously mentioned, to understand what options the patients and the doctors have. To understand if the extra fee is a desirable addition to the current payment method, the patients' and general public's opinion will have a great influence. Therefore, this report will provide, next to the already provided analysis of these impact factors, a research proposal concept for a willingness to pay study.

II. THEORY AND METHOD

2.1 Willingness to pay research

Willingness to pay (WTP) research is an important market research tool that plays a large role in pricing decisions and new product development (27). Furthermore, it can be used to forecast customer responses to price changes and to determine demand. WTP research can be divided into "revealed preference" and "stated preference". In a "revealed preference" methodology information is derived from market data or experiments. For the purpose of this study we are more interested in the "stated preference" type, which gathers its information from direct or indirect surveys.

2.1.1 Direct surveys

In direct surveys, participants are asked to state how much they are willing to pay for a product or service, while in indirect surveys a rating or ranking for different products will be determined. Customer surveys are a direct survey method in which customers are asked what the minimum and maximum price is that they are willing to pay. The maximum price can be determined by asking above what price the customer would definitely not buy the product because they can't afford it, or they don't think it is worth the money. The minimum price is determined by asking the customer below what price they would definitely not buy the product because they start to suspect the quality of the product (27). Additionally, customers could be asked to give a reasonably cheap price and a reasonable expensive price.

While this type of research has many benefits, such as low cost and not particularly time consuming, one of the flaws needs to be discussed. The perceived value of the product as determined by customers can fluctuate greatly, which could be especially the case in health care. When customers become aware of the market price of the product, their perceived value changes (27). Many people are unaware of the costs made in surgery; therefore, it could be beneficial to provide the survey participants with a description of costs of regular reconstructive surgery. This will eliminate differences in the willingness to pay for the extra fee due to a lack of knowledge of regular costs.

2.1.2 Indirect surveys

Alternatively, an indirect survey can be used to eliminate the problem of misjudging the price. In an indirect survey the participant is asked to decide if a specific price for a product is acceptable instead of asking the participant to directly assign a price. The participant would then decide on their preferred choice, choosing from the regular surgery and the alternative. In addition, the patient participants can be instructed to rate the product on a 1-7 attractiveness scale or 0-100 purchase likelihood scale (27).

2.2 Return on investment

Whenever an investment will be made in healthcare or any other sector, it is important to take the return on investment (ROI) into account during planning. The ROI is a measure of productivity of an investment (28). It can be calculated by dividing the income (excess of revenues over all related expenses) by the cost of the investment. The cost of the investment includes any training, facilities, and additional materials needed. The income is related to the reimbursement

for services and potentially the extra fee.

2.3 Scenario analysis

By using scenario analysis, the most cost-effective scenario can be selected (29). These scenarios can be made in the most optimistic way or provide a worst-case scenario. The impact of factors such as the capacity, number of surgeons employed, duration of surgery, number of operating rooms, all contribute to where on the cost-effectiveness plane a scenario will end up. Therefore, for the purpose of this study these impact factors will be assigned varying values in different scenarios to select the most beneficial option.

III. PRELIMINARY RESULTS

3.1 Legal constraints

The Minister of VWS introduced the instrument 'conditional entry into the basic healthcare package' as of 1 January 2012. Conditional entry will apply to new and existing forms of health care, whereby the condition is that data must be collected on effectiveness and/or cost-effectiveness, eventually to make a decision on permanent entry into the package, termination of the conditional entry, or advising the Minister on removal from the package.(30)

The effectiveness requirement is statutorily supported (the concept of 'established medical science and medical practice' in the Zvw), while cost-effectiveness is not. This means that the procedures for conditional entry/reimbursement will differ regarding treatment effectiveness research and cost-effectiveness research. The first case involves conditional entry into the package: this means that health care that does not fulfil the statutory criterion is nevertheless accepted – temporarily – into the package on the condition that data are collected

about the efficacy of that care. In principle, health care that is effective is included in the package, though it may be desirable to collect cost-effectiveness data. In that case, one does not speak of 'entry into the package' but rather of conditional reimbursement.

The assessment of medical care prior to 'acceptance' into the package is not standardised; interventions are automatically included: the legislator trusts care-providers only to provide care that complies with the 'established medical science and medical practice' criterion. This is generally the case, but in the case of innovative care, there is a tendency to supply such care before sufficient data are available. This improper 'acceptance' often goes unnoticed. The instrument conditional reimbursement can identify such health care and ensure the 'managed introduction' of interventions. (20,31)

From the foregoing discussion on the reimbursement of a treatment under basic/supplementary healthcare insurance packages and the role of the actors in the healthcare system, it can be concluded that legally 'conditional reimbursement' is an exception in the Healthcare Insurance act which allows for a treatment to be included in the basic healthcare insurance content. Currently, this is the case for breast reconstruction surgery post breast cancer compliant with the conditions laid down in the statute (autologous fat transplant).

The fact that the reconstructive surgery has been included conditionally means that more evidence on the treatment

effectiveness and cost effectiveness is necessary to be supplied to

the lawmakers to move it into the basic health insurance package. Another point to consider here would be that the clause defines the procedure in general terms. However, this definition doesn't consider the fact that the reconstruction surgery is more than transplanting body's own fat to the breast area in a surgical procedure.

3.2 Patient associations cooperation

We contacted a total of six patients' associations that advocate particularly for breast cancer. Some of them did not respond to any of our messages and calls, and the ones who did, argued that their association did not have the possibility to answer our questions (see questionnaire in appendix 1) because they did not have the necessary information on patient preferences regarding the payment of extra fees. After we contacted the patient associations, we concluded that there is a need to choose one association and build a more in-depth relationship with it, in order to work together towards an awareness campaign for breast reconstructive surgery and options for cancer survivors. The best patient association to contact is Borstkanker Vereniging Nederland (BVN; Breast Cancer Society), since they have the most extensive reach and an active involvement of their members. The association has a database of patients that are willing to participate in research efforts. BVN is willing to distribute a questionnaire for the willingness-to-pay research amongst their patients if the questions asked are acceptable and comply with the image of BVN. The exact conditions for them to participate in this research will need further deliberation.

IV. CONCLUSION AND IMPLICATIONS

4.1 Legal implications

As a long-term solution to the prevalent situation, compel the lawmakers to consider evidence the on treatment and cost effectiveness since the introduction of the procedure. This could be the main evidence in support of moving the treatment from conditional reimbursement to the main basic insurance package. Draw attention of lawmakers to the fact that the definition of 'autologous fat transplant' is in itself incomplete and is open to a broad interpretation. As the procedure medically involves transplanting the fat, operating on the blood vessels around the area, highlight the fact that nerves cannot be ignored in this process and hence restoration of sensation to the area is more of a necessity than a requested process. It could be argued by Maastricht UMC+ that restoration of sensation to breast is a normal part of the process and therefore the legislation should broaden the scope to include this aspect in basic insurance reimbursement.

Although the conditional reimbursement is reliant upon evidence of cost and treatment effectiveness to decide on inclusion in the basic healthcare package, there has an example in the Netherlands whereby the Ministry of Health was compelled to include pharmaceutical reimbursement in the basic insurance package despite the disease being orphan. Consider the case of Pompe and Fabry diseases where it was argued that due to astronomical cost of the medicine (€ 400.000 and € 700.000 a year for Pompe's, for Fabry-patients about € 220.000 a year), very little result was achieved and

hence should not be compensated. (32,33) This proposal by the Ministry drew attention from the media, patient organizations, doctors treating the diseases and the Health Ministry. Although these actors refused to participate in convincing the Ministry initially, once the news spread, the Health Ministry changed its decision and it resulted in the therapy being reimbursed. This example shows that even little evidence is still evidence and if the right voices of those that are in need of insurance reimbursement join forces, the Health Ministry can make decisions on including a treatment in the basic insurance package.(32)

4.2 Implications for future research

To understand if the extra fee for reducing waiting times and the addition of nerve coaptation to standard reconstruction is a desirable addition to the current payment method, the patients' and general public's opinion will have a great influence. Several steps need to be taken before and during the development of a research plan:

1. To gain the cooperation of Borstkanker Vereniging Nederland a discussion is needed on the contents of the to comply with the requirements given by the association.
2. It will need to be decided if an indirect or direct survey method will be used to assess the willingness-to-pay. Also, a choice should be made whether in addition to the study group consisting of patients, another group of participants from the general public should also be asked for the willingness-to-pay for extra fees.
3. The different possible scenarios will need to be reviewed in greater detail by providing information on the surgery capacity, waiting times, number of surgical staff, and number of operating rooms. This is necessary to correctly assess the feasibility of each scenario.

Therefore, in addition to an analysis of the impacting factors, this report provides a research proposal concept for a willingness to pay study Willingness to pay (WTP) research is an important market research tool that plays a large role in pricing decisions and new product development. Furthermore, it can be used to forecast customer responses to price changes and to determine demand.

ACKNOWLEDGMENT

The authors declare that the research was conducted in the absence of any commercial or financial connections that could be construed as a potential conflict of interest.

APPENDIX

The Appendix 1: Questionnaire sent to the patient associations

1. Do the patients know all the options they have to reconstruct their breasts?
2. Does the association provide such information?
3. Can patients contact your association for information regarding the procedures, hospitals, clinics, costs, insurance, etc. at the association?
4. Is the association currently advocating on issues regarding reconstructive surgery?
5. Are patients aware about the coverage of

reconstruction surgery by insurance companies?

6. Would patients be willing to pay an extra fee for better reconstructive procedures?
7. Would the patients be willing to pay an extra fee to reduce the time on a waiting list for a reconstructive surgery?
8. How good do you rate your information on breast sensation after reconstruction?
9. Is your organization aware of this procedure? Microsurgical nerve coaptation of the sensory nerve of the DIEP flap to the 2nd and 3rd intercostal nerve is a method to improve sensitization of the reconstructed breast (Cornelissen et al, 2018). This technique leads to an increased operating time by 15-30 minutes on average and led to no increased risk of complications (Beugels et al., 2017). Considering the average bilateral breast reconstruction operative time of 456 minutes, nerve coaptation will only extend operative time with 3.3-6.6%.
10. Does your organization's website provide information on nerve coaptation?
11. Considering the questions above on nerve coaptation, how do you rate the quality of information provided on breast sensation now?

Appendix 2: Draft of questionnaire

Patients will be contacted by the help of the Borstkanker Vereniging Nederland. Another option would be to contact patients currently on the waiting list for breast reconstruction or patients that have since in the Netherlands there is the system of public health.

Concept of indirect survey:

1. What is the maximum amount that you would be willing to spend for the addition of a breast sensation enhancing technique to the standard breast reconstruction paid for by the insurance?
2. What is the minimum amount that you would be willing to spend for the addition of a breast sensation enhancing technique to the standard breast reconstruction paid for by the insurance?
3. What do you consider a reasonably cheap price for the addition of a breast sensation enhancing technique to the standard breast reconstruction paid for by the insurance?
4. What do you consider a reasonable expensive price for the addition of a breast sensation enhancing technique to the standard breast reconstruction paid for by the insurance?
5. What do you consider a fair price for or the addition of a breast sensation enhancing? technique to the standard breast reconstruction paid for by the insurance.

To measure the willingness-to-pay of reducing the waiting list time for surgery the same concept can be used. In addition, questions can be split up on the level of reduction of the waiting list. For example, ask willingness-to-pay questions for a 1-3-month reduction and 4-6-month reduction in waiting time. These numbers can be altered based on the current waiting list.

Concept of direct survey:

The price for the addition of nerve coaptation to the standard procedure will need to be determined based on costs.

Patients will then be given the choice if they are willing to pay this extra fee or stick with the regular fully reimbursed reconstructive surgery.

The direct survey method could be the best option to determine if patients are willing to pay for the addition of breast sensation recovery, because of the patients lack knowledge of healthcare costs. In contrast setting an exact price for reducing waiting times will be challenging. Therefore, the indirect survey method is suggested for measuring the willingness-to-pay for reduced waiting times.

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