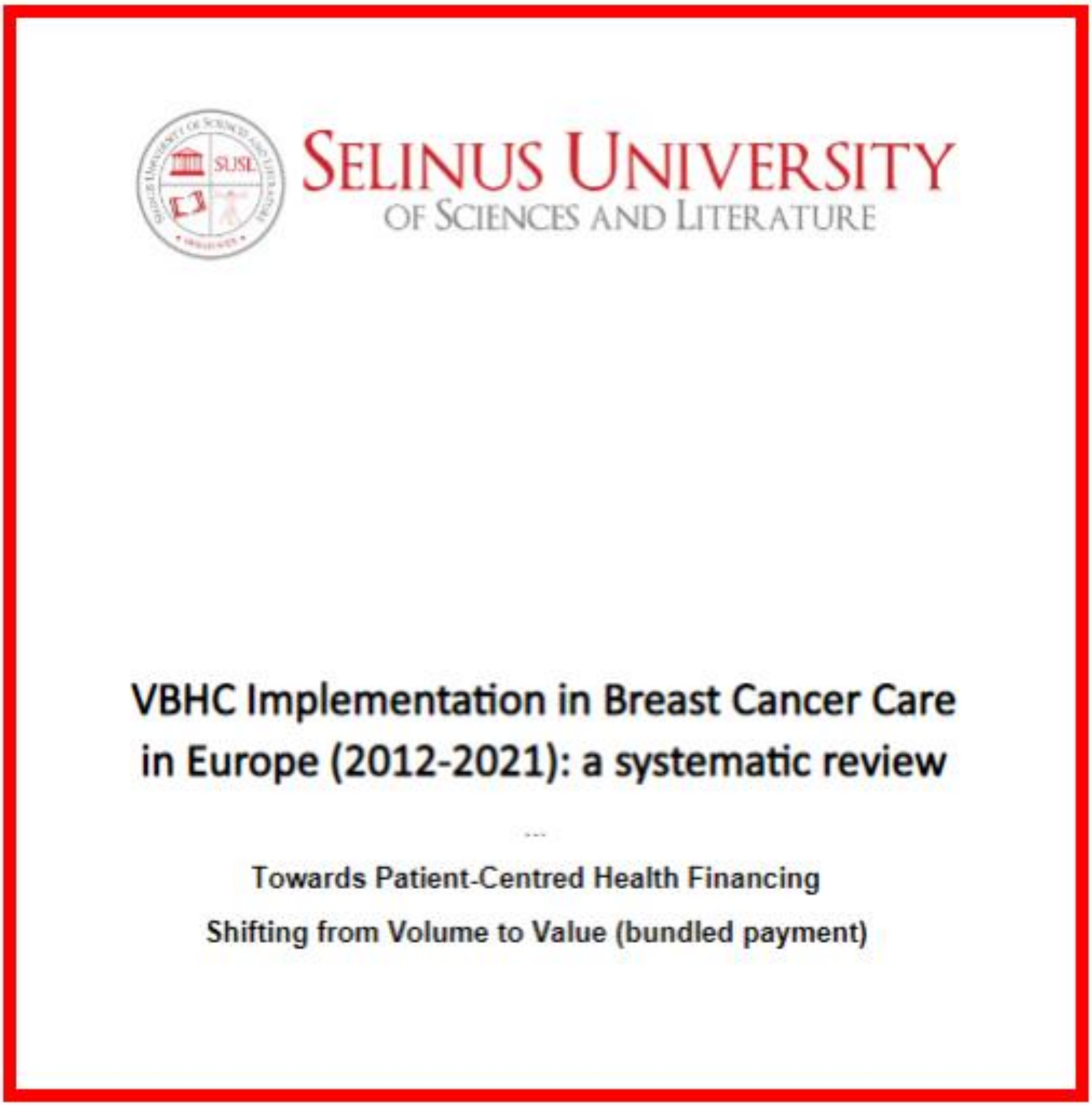

SELINUS UNIVERSITY
OF SCIENCES AND LITERATURE

VBHC Implementation in Breast Cancer Care in Europe (2012-2021): a systematic review

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Towards Patient-Centred Health Financing
Shifting from Volume to Value (bundled payment)

By Elisabeth de Sousa Maron

Health Care Cost Analyst Engineer

DECLARATION

I do hereby attest that I am the sole author of this thesis titled: "VBHC Implementation in Breast Cancer Care in Europe (2012-2021): a systematic analysis", submitted for the Award of Doctor of Philosophy (PhD) in Health Care Management, Faculty of Business and Media, at Selinus University of Sciences and Literature. This dissertation is my original work, no part of it has been presented for another degree in this university or elsewhere. The contents in this thesis are the result of the research that I have done on the topic and my experience as a Health Care Cost Analyst Engineer. I hereby declare that all the information in this research was obtained and presented in accordance with academic rules and ethical conduct. The material, articles and data referred in the dissertation have been cited in the thesis.

Date: April 2023

Elisabeth de Sousa Maron

student number:

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CITATION

"If you talk to a man in a language he understands, that goes to his head.
If you talk to him in his language, that goes to his heart."
Nelson Mandela

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All my gratitude and thanks to my avos ,Manuel and Maria, my parents, Manuel et Gisela, who gave birth to me and to Lady Germaine who shared her passion for studying (Mont-Saint-Michel France).

DEDICATION

I dedicate this thesis to my dear uncle Orlando
and my lovely daughter Lysa-Marie.

ABSTRACT

Background: European economy, such as global economy, is fighting against the burden of healthcare costs in an environment of covid-19 pandemic. Healthcare system was completely disturbed by the coronavirus pandemic. Those rising costs are due to increased life expectancy, prevalence of chronic diseases. Over the last decades, different management concepts have been developed and practiced maintaining the explosion of these expenses, such as evidence-based decision-making, Lean and cost reduction. But this proved ineffective in the face of soaring healthcare costs. Healthcare urgently needs a management which controls costs while respecting value, as asked by OECD in its 2017 report - “Wasteful Spending in Health”: “Health spending is at best ineffective and at worst wasteful” (1) Policymakers have to rebuild a healthcare delivery and reimbursement policy, such as Value-based health care (VBHC) defined by Prof. Michael Porter and Prof. Elizabeth Teisberg (5). Cancer is a group of more than 200 diseases. In 2020, 2.7 million people in the European Union were diagnosed with cancer. And 1.3 million people died from it (8). Even if Europe aggregates a tenth of the world’s population, it accounts for a quarter of the world’s cancer cases. In 2018, European cancer spending attained €199 billion (EU-27 plus Iceland, Norway, Switzerland, and the United Kingdom) (10). The breast cancer is one of the most frequent reasons of death among women (15). An increasing prevalence of women with breast cancer come from both the increased incidence of breast cancer and the improved breast cancer survival rates. This poses additional challenges for the medical community, as breast cancer and its treatment can adversely alter the physical, psychological and social well-being of patients, both during and after treatment (131). In recent years, there has been a shift from a more generic care way to a more patient-centred approach to care (132). With patient-centred care, cancer care has turned into more targeted on the person needs of breast cancer patients, both clinically and in terms of personal values. This patient-centred delivery of care is the potential of the foundation of value-based healthcare (VBHC).

Methods: The methodology of the study, implementation of VBHC in Breast Cancer Care in Europe (2012-2021), is designed by a systematic review (179 scientific articles) followed by a qualitative content analysis with NVIVO version 11 of the 6 steps of the Value Agenda in Breast Cancer Care in Europe.

Results: The results show that VBHC in Breast Cancer Care in Europe in ist long way to be fully implemented. Bundled payments barely exist. And patient-reported outcomes are the spearhead of the VBHC implementation in Breast Cancer Care in Europe (2012-2021).

Conclusion: Most European countries with high level of spending on healthcare also tend to have a presence of outcome-based payment approaches, such as in Breast Cancer Care. Growing consideration is being paid to reporting patient outcomes in a standardized manner in Breast Cancer Care.But, the European Health Care systems remain based on a supply-driven model instead of a patient-centered model.

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ACRONYMS

ABC	Activity-Based Costing
ASCO	American Society of Clinical Oncology
BCS	Breast-Conserving Surgery
BCG	Boston Consulting Group
BCT	Breast-Conserving Therapy
BMJ	British Medical Journal
BPT	Best Practice Tariffs
BR-23	PROMs for breast cancer
BRCA1	BReast CAncer gene 1
BRCA2	BReast CAncer gene 2
C-30	PROMs for Cancer
CCGs	Clinical Commissioning Groups
COPD	Chronic Obstructive Pulmonary Disease
CROMs	Clinician Reported Ourcome Measures
DALYs	Disability-adjusted life years
DICA	Dutch Institute for Clinical Audit
DiGa	DiGa refers to health legislation and rules in Germany which came into effect on December 19, 2019
EBM	Evidence-Based Medicine
EMA	European Medicines Agency
EML	Essential Medicines List
EORTC	European Organization for Research and Treatment of Cancer
ER	Estrogen Receptor
EU-27	27 European Union countries
EUHA	The European University Hospital Alliance
EFTA	European Free Trade Association
EU4Health	The Fourth EU health programme
EUHA	European University Hospital Alliance
EUSOMA	The European Society of Breast Cancer Specialists
EXPH	The Expert Panel on effective ways of investing in Health
GBCI	Global Breast Cancer Initiative
GLOBOCAN	Global Cancer Incidence, Mortality and Prevalence
HRQoL	Health-Related Quality of Life
ICS	Integrated Care Systems
IARC	International Agency for Research on Cancer
ICHOM	International Consortium for Health Outcomes Measurement
INEK	The Institut für das Entgeltsystem im Krankenhaus
IQWIG	Institute for Quality and Efficiency in Healthcare
IT	Information Technology
IPUs	Integrated Practice Units

JAMA	It is a monthly peer-reviewed medical journal published by the American Medical Association.
JRC	Joint Research Centre
MRI	Magnetic Resonance Imaging
NCDs	Noncommunicable Diseases
NDR	National Data Resource
NGO	Non-Governmental Organisation
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NQR	the National Quality Registries
OECD	Organisation for Economic Cooperation and Development
PALB2	Partner And Localizer of BRCA2
PaRIS	Patient-Reported Indicators Survey
PC	Palliative Care
PCPs	Primary Care Physicians
PR	Progesterone Receptor
PREMs	Patient-Reported Experience Measures
PROs	Patient-Reported Outcomes
PROMs	Patient-Reported Outcome Measures
QoL	Quality of Life
RWE	Real-Word Evidence
R&D	Research and Develpment
RT	Radiation Therapy
SMR	Service Médical Rendu
TDABC	Time-Driven Activity-Based Costing
USA	United States of America
VBCP	Value-Based Care Pathways
VBHC	Value-Based Health Care
WHA	World Health Assembly
WHO	World Health Organization

LIST OF FIGURES

PART I INTRODUCTION AND LITERATURE REVIEW

Chapter I-1 Introduction

I-1.1 Background of the study

Today, the global economy is suffering from not only an energy crisis but also a significant healthcare burden due to COVID-19, increased life expectancy, a rise in prevalence of chronic diseases, development of diagnosis and treatments with inappropriate care, errors and frauds. Despite the tremendous work of well-trained physicians and the investments in state-of-the-art healthcare facilities, Global studies of World Health Organization (WHO) and the OECD show that 30% of health spendings gives no valuable impact for patients (2): spendings are wasted on unnecessary aggravations, needless treatments or wasteful organization. Over the last decades, different management concepts have been developed and practiced maintaining the explosion of these expenses, such as evidence-based decision-making, Lean and cost reduction. But this proved ineffective in the face of soaring healthcare costs. Robust evidence and survey point out that an important part of healthcare expenses is ruined on suspicious or useless treatments. In a sustainable strategy, Healthcare urgently needs a management which controls costs while respecting value, as asked by OECD in its 2017 report - “Wasteful Spending in Health”: “Health spending is at best ineffective and at worst wasteful” (1)

Nonetheless, in recent times, an advanced strategy has come to light to solve these problems. Thus, healthcare stakeholders have started to reconsider their operating model to target on enhancing healthcare value, patients’ meaningful outcomes: patient-centricity.

Although this interest in placing the patient at the centre of healthcare seems new, William Osler took up this point of view more than a century ago, insisting that above all physicians cared firstly for their patients before defining the exact pathology. In 1932, A.H. Gordon underlined the commitment to “treat a patient as a person, not merely as a representation of medical, surgical or pathological material.” And later Avedis Donabedian, a physician, founded the study of quality in health care and medical outcomes, known as The Donabedian Model of care (3). This model keeps on being the dominant paradigm for assessing quality of health care (4).

I-1.2 Statement of the problem

These last decades the way to meliorate quality has been transformed. Successively, the triptych Donabedian passed: “structure, process and outcome”. Lately, the latest focus was on outcomes, such as Value-Based Health Care (VBHC). Over the last 15 years, concomitantly, countries have been trying to turn healthcare from a disease-focused system to a health and wellness-focused system by embracing the VBHC agenda.

Healthcare system was completely disturbed by the coronavirus pandemic. Policymakers have to rebuild a healthcare delivery and reimbursement policy, such as Value-based health care (VBHC) defined by Prof. Michael Porter and Prof. Elizabeth Teisberg (5). In the United States of America, policymakers have been primarily committed to modifying healthcare from fee-for-service to pay for value (6). In Europe, the more public-run system has been targeting patient care organisation by designing outcome platforms to manage quality enhancement and care suitability (7).

I-1.3 Objectives of the study

Cancer affects everybody, patients, families, friends, caregivers. Cancer is a group of more than 200 diseases, from any human body organ whose abnormal cells spread destructively to infiltrate into adjacent parts of the body until turning into metastases (major cause of death from cancer). In 2020, 2.7 million people in the European Union were diagnosed with cancer. And 1.3 million people died from it (8). On earth, cancer incidence rates (number of new cancers) are forecasted to raise from less than 20 million per year to more than 30 million per year by 2040. Thus, cancer is still a preeminent cause of decease (10 million deaths worldwide in 2020) (9)

In 2018, European cancer spending attained €199 billion (EU-27 plus Iceland, Norway, Switzerland, and the United Kingdom) (10). Unfortunately, the cancer burden keeps on expanding globally with terrific physical, emotional and financial pressure on patients, families and health systems. Obviously, the principal way to fight this cancer burden is by knowing the type of cancer and setting up state-of-the-art methods of prevention (early detection through screening) and diagnosis, what boost cancer care costs but ensue in a better chance of survival.

Even if Europe aggregates a tenth of the world's population, it accounts for a quarter of the world's cancer cases. European deaths from cancer are predicted to escalate 24% by 2035, turning it into the main cause of death in Europe (11). The societal economic consequences of cancer in Europe are predicted to excel €100 billion per year (12). **Europe's Beating Cancer Plan** (12), created for a more robust European Health Union, fights against the European burden of cancer with specific actions while entirely complying Member States' responsibilities in health policy (13). **Europe's Beating Cancer Plan** (12) wants to engage all cancer pathway, to do so it is designed around 4 main actions: prevention, early detection, diagnosis and treatment, cancer patients and survivors' quality of life. It notably describes processes to reduce the Covid-19 pandemic's consequences on cancer care. It also favours structural progresses towards a more sustainable cancer care pathway. Thereby, patient-centricity is at the heart of **Europe's Beating Cancer Plan's** strategy with patients' concern and well-being. Furthermore globally, the EU4Health program (14) and the World Health Organisation (WHO) with its International Agency for Research on Cancer have been building cancer care management collaboration.

The breast cancer is one of the most frequent reasons of death among women (15). Moreover, in 2020 numbers of new cases per year shows that breast cancer is the leader one. Worldwide, according to WHO, a breast tumour is diagnosed every 30 seconds. ASCO and WHO, as partners, will build a collaborative way to help WHO Member States and cancer centres with better access to quality care by for example creating evidence-based quality indicators (16). Facility-level improvement activities will be connected to national health strategies.

Relevance of the topic in European Healthcare Management

If Europe only inhabits 10% of the world's population, it aggregates a quarter of all cancer cases (17). Obviously, cancer turns to be a tremendous danger for Europe's citizens and systems. "Each year, 2.6 million people in the EU-27 are diagnosed with cancer" (18). This figure is forecasted to raise expeditiously due to ageing populations, unhealthy lifestyles and poor environmental conditions. Without structural actions, the number of cancer cases in Europe will keep on growing by 25% by 2035. Even though during the last decades cancer survival rates have ameliorated. 1,2 millions of European people still die from cancer in the EU-27 each year.

I-1.4 Scope of the study

The research question and the general objective of this work are presented as follows: describe and analyse the 6 steps of the value agenda achieved in Europe in Breast Cancer Care, the missing steps "gap" in the implementation of value-based interventions in breast cancer care in Europe.

In order to achieve the general objective, the following specific objectives have been set:

1st goal: Identify completed steps for implementing value-based interventions in breast cancer care in Europe

2nd goal: Analyse the missing steps for setting up breast cancer care bundle payments in Europe thanks to value-based healthcare.

I-1.5 Methodology of the study

The methodology of the study, implementation of VBHC in Breast Cancer Care in Europe (2012-2021), is designed by a systematic review followed by a qualitative content analysis of the 6 steps of the Value Agenda in Breast Cancer Care in Europe.

I-1.6 Structure of the Study

The remainder of this thesis is structured as follows: in Part I : Introduction where is discussed the background of the study, the theoretical core concepts of VBHC and the burden of breast cancer. Part II, the research methodology is presented. In Part III, the results of this study are drawn with figures and discussed. In part IV, the conclusion with recommendations are given.

Chapter I-2 Literature Review

I-2.1 Introduction

During the last years, Value-Based Health Care (VBHC) has been introduced by Michael Porter and Elizabeth Teisberg (5) of the Harvard Business School (USA) and elevated as the modern method of undertaking the healthcare defiant sector while meeting the European standards of universality and equality.

I-2.2 VBHC

I-2.2.1 VBHC defined by Prof. Michael Porter and Prof. Elizabeth Tiesberg

I-2.2.1.1 Introduction of VBHC in theory

The VBHC model establishes the achievement of more effective emulation between healthcare stakeholders, by boosting value for patients explained by health outcomes in relation to costs: key features on the model and prerequisites for the value-based emulation. VBHC recommends reimbursement models, outcomes measurement and other suggestions. In theory as it was set for the US market, VBHC lays on a free market with providers' competition and freedom of patients to achieve higher health quality and cost reduction. As the European healthcare market is regulated by legal structures highlighted by equal access to healthcare rather than a free market. At global policy level, it may also be the reason why the concept of VBHC has been granted several understandings and practices. Thereby at bottom, the VBHC has usually been handled partwise at an hospital level (microeconomics) and not at a national health policy level (macroeconomics) such as Sweden.

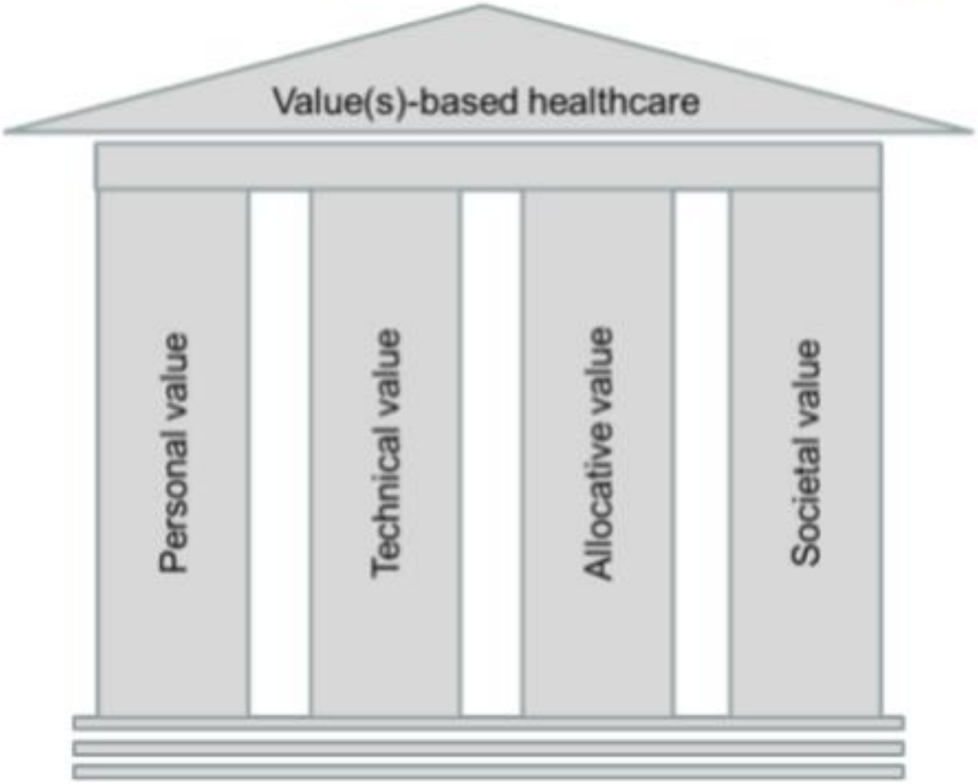
In 2006, Prof Michael Porter and Prof Elizabeth Olmsted Teisberg (5) launched their book “Redefining Health Care” with new healthcare market view. This book announced a few key fundamentals to transform healthcare into more transparent care with quality focus, improving patient value. The patient value equalizes patient relevant outcomes produced per unit of money invested.

I-2.2.1.2 What is VALUE ?

What does value mean?

Value can be defined in diverse ways in different circumstances. Healthcare professionals deliver value for patients, services and society, by reaching the best outcomes at the lowest cost. The European Commission defines value with four pillars upon which VBHC is built: personal value, technical value, allocative value and societal value (19) (figure 1)

figure 1 : the four value pillars for a value(s)-based healthcare in Europe



Personal value is achieved when care outcome performs their personal goals. Healthcare professionals deliver value across shared decision making and conversation (to reduce information asymmetry) about the chances of benefits and the risks of harms of various treatments. Thus, patients can make informed decisions. And providing personal value advises about the relevant employment of accessible resources while providing care that really matters to people.

Allocative or population value means how resources are shared among the population. It should be equitable and transparent across the care pathway for suitable and fair use of resources meeting the needs of the population.

Technical value guarantees that the allocated resources are optimized without waste. Technical value examines the best use of resources for a specific subgroup of the population with a particular care need or medical condition. Technical value necessitates a complete correlation between the demands of service users and the supply of service. If there is exaggerate use of a treatment or care department, patient do not benefit from needed care, value is not delivered. Then, patient can be endangered to harm.

Societal value considers the expanded impact of healthcare in society.

The meaning of value in health care

The concept of value in an important current issue in the field of health care. Personal needs, preferences and ethics have influenced the meaning of value, which consecutively has been altered by different cultures or historical periods (20). The need to find better methods and means to transfer inducements from volume to value has driven patients, physicians, policymakers and other stakeholders to target their attention on the significance of value and its key characteristics (21). Although an uncontested agreement on the meaning of value has not yet been reached, it is mainly recognised that values in health care can be designated as normative guidelines for appraising actions or conditions and for motivating the decision-making process (22-24). Various studies have called attention to the fact that the definition of value varies with the associated sample: the values of physicians, frequently, do not coincide with the values of patients.

Previously, value has always been determined by means of clinical outcomes like enhancing blood test parameters (17). Prof. Michael Porter and Prof. Elisabeth Teisberg (2006) (5) thus point out that the stakeholders have so far measured the wrong outcomes and therefore pursued the wrong goals. Porter and Teisberg recommended the VBHC, which is assumed to be revolutionary in the healthcare history.

Figure 2: The value equation in value-based health care

VALUE = PATIENT OUTCOMES / COSTS

Source: Porter & Teisberg (2006)

I-2.2.1.3 What is VBHC In general ?

In VBHC, the healthcare delivery system is centred into the patient, where all stakeholders are concentrated on accomplishing the best patient health outcomes per euro spent, at a medical condition level and over the entire cycle of care, which is considerably substantial. To do so, conforming to Porter and Teisberg (2006), stakeholders need to follow the 6 crucial steps to perfectly achieve the VBHC (VBHC agenda):

1 – Integrated Practice Units (IPUs): Porter and Teisberg (2006) (5) disagree with the classic organisational healthcare structure, because it is established on medical specialities and care supplies. Instead, stakeholders should restructure care by getting away from a hospital segmented in medical specialities like Oncology, to a hospital managed in integrated practice units, like breast cancer IPU.

2 – Quantify outcomes and costs: It is important to not only measure clinical and process outcomes but also patient reported outcomes and the full cycle of care’s cost, to settle rigorous measurement. This defines what really matters for patients. In order to enable competition between providers based on results, outcomes and costs should be measured for every patient over the full care cycle (Porter & Teisberg, 2006) (5). Cost measurement should also comprise the entire care cycle, with all expenses traced to the individual patient (Porter & Lee, 2013) (6).

3 – Enforce bundled prices: by defining one price for the entire cycle of care. Porter and Teisberg's basis affirm the use of bundled payments instead of fee-for-service payment for discrete services. Fee-for-service payment had been the principal payment mechanism. Bundled payments should be defined previously and for full care cycles (Porter and Lee, 2013) (6). Bundled payments are also announced to stimulate teamwork and coordination around patients' care needs. It will also decrease administrative costs.

4 – Integrated systems: Stakeholders must integrate care through a network of hospitals departments. Thus, patients will be attended by the best providers although geographically distant. This organisation will promote outcomes improvement and cost reduction. Porter and Teisberg claim that providers should specialise in their most effective area.

5 – Geographically expand: by affiliating with community providers to broaden the extent of IPUs, Hospitals will be able to administer outstanding services. Furthermore, providers should be in multiple sites and effectively allocated, for example by saving high-cost centres for complex medical conditions. Porter and Lee (2013) (6) assume that virtuous competition between providers, thanks to patients' decision-making with outcomes measurements' publicly available, should consequently authorize a geographic expansion.

6 – Set up an IT platform: to integrate all patients data over the complete pathway. Stakeholders, from providers to payers, will be able to communicate effectively with the same tools. In the end, this VBHC agenda should be supported by Information Technology (IT) systems (Porter and Teaisberg 2006) (5) the whole patients'data should be compiled in a single server to be accessed by VBHC stakeholders (Porter and Lee 2013) (6).

I-2.2.1.4 The Value-Based Health Care (VBHC) paradigm

At Harvard Business School, M.L. Porter and E. Teisberg built an innovative value-based healthcare model, presented as "a revolutionary framework redefining healthcare competition based on patient value" (5). A Value-Based Health Care (VBHC) should reference to three fundamental standards (26)

First, the appropriate goal for each stakeholder should be greater health for their patients, not more treatments. Enhancing access to poor care or including costs should be supplanted by the paramount goal of ameliorating patient value, described as the “best health outcomes achieved per dollar spent” (27). Health outcomes mention the results performed by the patient throughout the care cycle, the authentic results of care about the real patient performance. The costs designate the comprehensive costs of care for the patient’s condition, the existing cost of delivering care, and the resources needed to provide the care. Consequently, enlarging patient value signifies reinforcing quality, that is rising health outcomes without developing costs or reducing costs and without jeopardising outcomes (6)

Second, the provision of treatment should depend on the medical conditions and on the treatment the patient needs to go through. Every stakeholder performs a leading role in deciding the convenient patient care pathway, and the complete outcome stems from the quality of all services provided. Finally, outcomes must be computable and filed (28). Data should be retrieved throughout the patient care cycle, as outcomes obtained are more effective measures than the number of services provided. It would not be feasible to know beforehand if they were used correctly and remarkably. Furthermore, the results must be interpreted according to the costs insured throughout the care cycle: reducing the costs without taking the outcomes into account would be perilous and doomed to failure (26).

I-2.2.2 The Value Agenda

These principles underpin value transformation based on patient needs, achieved health outcomes, and collected costs in healthcare delivery organisations that pursue the full cycle of care for particular medical conditions. Porter and colleagues (2006) determined this strategy as the “Value Agenda” (5, 6). This strategic agenda has six interconnected and reciprocally reinforcing constituents. If they were proceeded together, the fulfilment of a new model of health care delivery would be more facile and quicker (Figure 3).

Figure 3: The Value Agenda. the model has been taken by Porter and Lee (2013)

The Value Agenda

The first point of the agenda: Porter and Teisberg claim that the classic organizational structure of health care delivery, which is established on medical specialities and care delivery, is obsolete. Health care should be managed around the customer, the demand side: the **patient’s medical condition**. In such an organisation centred around medical conditions, the employees (clinical and nonclinical) must work as a team (**integrated practice units IPU**) to deliver the entire care cycle for the patient’s medical condition. (Porter & Teisberg, 2006) (5).

The second point of the agenda: Porter and Teisberg defend that exact measurement is fundamental for ameliorating the performance of the healthcare sector. To allow competition between providers based on outcomes, outcomes and costs need to be measured for each patient across the care cycle (Porter & Teisberg, 2006) (5). The choice of outcome's measures should be decided based on each medical condition and the patient's earliest state, sometimes likewise mentioned to as a risk factor for its likelihood of altering patients' recovery. A distinct set of outcomes are determined and associated based on specific diseases: initial patient indicators (such as disease type, age...), acute care outcomes, complications or co-occurring conditions shape the outcome overall full care cycle. To determine what kind of measures should be suitable for a particular disease, providers require comprehending the most appropriate health circumstances and the group of services involving patient outcomes, the short- and long-term repercussions of care, and the risk factors that can alter the patient's condition (29)

The third point of this comprehensive strategy for value change involves an innovative category of payment way: A value-based healthcare system should use **bundled payment** to comprehend the full cycle of care for each type of disease (acute, chronic or preventive condition), a complete set of services necessary to treat the patient's medical issue. In this model of payment, providers must first anticipate the entire patient experiment across care settings and between episodic visits, and therefore translate that into a total cost of care including all expenses for the patient.

The fourth point of the Value Agenda is to integrate the delivery of care through distinct facilities to remove fragmentation and duplication of care. To optimize the types of care provided in each location, an integrated care delivery system needs to determine the purpose of the services provided and the centralization of the volume of analogous treatments in fewer locations depending on the medical condition and its acuity rank, the costs and concentration of resources and the requirement of availability.

The fifth point of the Value Agenda underlines that providers should practice exclusively in fields where they are the most effective. Furthermore, providers need to be spread across multiple sites by efficiently distributing care through their facilities, such as keeping high-cost centres for complicated medical conditions. Care pathways' integration through locations must be guaranteed. Patients make competition among providers. Patients accomplish decisions based on publicly available outcome measures. It should therefore enable superior providers to extend geographically (Porter & Lee, 2013) (5). Thus, this integration would be more accomplish through the appliance of the fifth step of this strategic agenda: the expansion of services across the location. Furthermore, IPUs and local facilities will augment their value: IPUs could spread their regional reach, prorate management fees and income, or complicated cases. Society providers would profit from the knowledge, know-how and fame of the linked IPU and generally meliorate their market.

The sixth point of the Value Agenda. To execute all these five components, it is essential to have an information technology platform that can support providers to integrate care throughout the care cycle, in order to better link the diverse facilities and IPU across geography or patients to the process. Effectively, Porter and Teisberg affirm that IT systems should permit patients to be tracked through care pathways, employing standardized terminology. This platform should be patient-centred with a comprehensible and standardised terminology. All data, such as physicians' notes, images, chemotherapy orders, lab tests, should be saved in a single virtual location available to all parties committed in the patient's health care (Porter & Lee, 2013) (6).

These interconnected and organisational requirements move the healthcare system from volume-based care to value-based care.

This model supplants the disorganized healthcare system with the opening of Integrated Practice Units (IPUs) where each medical condition or group of related conditions is treated by a multidisciplinary team of clinical and non-clinical providers qualified to deliver care to patients and inpatients.

The ongoing system is built around the rendered services, doctors and tools. This agenda emphasises the organisation of care around the problem and needs of patients. Each medical condition is an interconnected set of patient medical circumstances and potential aggravations that happen frequently and associate various specialities and departments (patient education, commitment and follow-up).

Uncoordinated consecutive visits to various providers and diverse services would be turned into integrated, high-quality care within the same organisation. Beyond clinical condition, they contain patient education, commitment and follow-up programs. Each patient's health outcomes and costs should be continuously registered, depending on care. The outcomes should include the full cycle of care for the medical condition and trace the patient’s health status once care is achieved. The measured outcomes can be categorised into a three-level hierarchy: the state of health achieved, the process of recovery, and the sustainability of health (Figure 4)

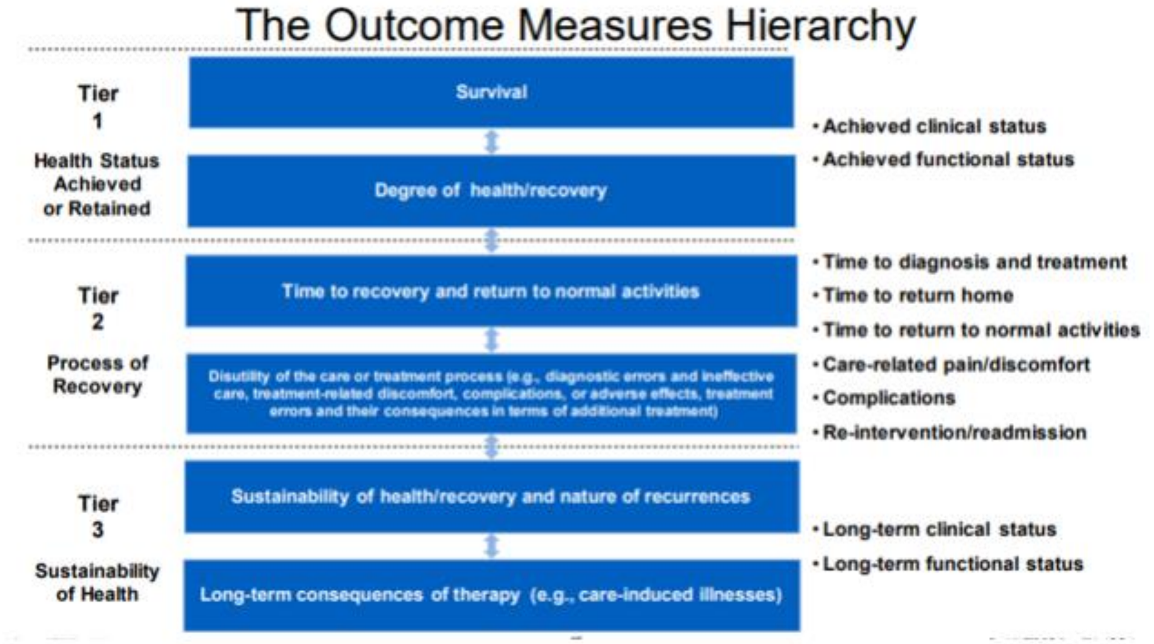


figure 4 : the Outcomes Measures Hierarchy.
the schema has been taken by Porter 2012, What is value in health care ?

<u>The Outcomes Measures Hierarchy</u>

Each tier contains two general levels with different outcomes measures of patient health, each of which is measured at a different time by various metrics.

<u>The patient health status (Tier 1)</u> contains survival or mortality and obtained recovery (clinical and functional status).

<u>The recovery process (Tier 2)</u> is consisted of time needed to reach recovery during the care cycle (e.g, a phase of diagnosis, treatments, follow-up) and the disutility of the care process. “This last dimension includes missed diagnosis, failed treatment, discomfort, ability to work or function normally while undergoing treatment, short-term complications, retreatment, and errors, together with their consequences”.

Tier 3 contains sustainability of health outcomes reached by referring to the degree of health kept, probable disease recurrences and long-term complications, or new health issues linked to previous treatments (29).

Furthermore, stakeholders should collect the total of expenses linked to the entire medical condition: the resources involved in caring for the patient should be associated with the cost of providing each of them, such as staff, equipments and administrative resources.

I-2.2.2.1 VBHC Agenda step 1 - IPU

I-2.2.2.1-A Care integration

An Integrated Practice Unit (IPU), as described by Porter, is defined as "organised around the patient and providing the full cycle of care for a medical condition, including patient education, engagement, and follow-up and encompass inpatient, outpatient and rehabilitative care as well as supporting services" (30)

This always ensues in care management based on intermediate outcomes, which requests both transparency and coordination over the definitive patient outcome to prevent suboptimization. These considerations drive us to a subdivision of medical conditions, from which the most rational care organization model for a patient pathway can be established.

The organizational model can be implemented internally by a definite healthcare provider if the patient journey (or relevant part of it) is particularly inside their own organization. Moreover, it can be implemented between multiple healthcare providers. The homogeneity of the patient group and the number of disciplines related are the decisive factors for the most logical care organization model of a patient pathway.

I-2.2.2.1-B Care pathway

Value Based Healthcare clearly aimed to focusing on reaching the highest value defined by patients to ameliorate healthcare financially and stakeholders' perspective. Value is then interpreted as **"health outcomes achieved that matter to patients relative to the cost of achieving those outcomes" (Porter & Lee, 2013) (6).** Porter

(2010) described patients' outcomes in a three-tier hierarchy (figure 4): health status, process of recovery, health sustainability.

A few authors have already explained methodologies to build care pathways, such as Campbell, Hostchkiss, Bradshaw, Porteous in 1998; Vanheacht and Sermeus in 2002, Panella, Marchisio and Si Stanislao in 2003, Vanhaecht and al in 2011. Campbell determines two principal dimensions of quality of care for individual patients: "access and effectiveness" (31). Based on previous interpretations of regular care pathways (De Bleser, et al., 2006; Vanhaecht, De Witte, & Sermeus, 2007; Kinsman, Rotter, James, Snow, & Willis, 2010; Porter, 2010; Porter & Lee, 2013), "Value Based Care Pathways (VBCP)" are characterized by the organization off all the activities of the interdisciplinary team carried out throughout the care cycle for a group of patients and a specific medical condition on evidence-based medicine (EBM) guidelines with the ambition of attaining the highest patient value. Value Based Care Pathways make the organization of care activities explicit. VBCP simplify communication between members of the multidisciplinary team and with patients and families. A VBCP synchronises the roles and chain of activities of the multidisciplinary care team across care departments and organizations, patients and their loved ones. In addition, it combines documentation, monitoring and assessment of variances and outcomes and classifies the needed resources for care delivery.

Porter and Lee (2013) (6) demonstrate that the health care system must move from a fragmented system to a coordinated patient-centred care delivery for each particular medical condition. Moreover, healthcare providers should have for each medical condition the shared target of reaching the best outcomes at the lowest costs, namely the highest value for patients. Coupling Value Based Healthcare with care pathways will focus care providers on the outcomes at the end of a patient's care process and across departments and care organizations. The target on outcomes instead of the current aim at service volumes will stimulate healthcare professionals to meliorate the value delivered to patients instead of standardizing processes to handle higher volumes. Restructuring work from the current "silo-ed" organization to one in which dedicated multidisciplinary teams deliver and monitor the full cycle of care will lead to secure treatments, improved outcomes and inferior costs (Porter & Lee, 2013) (6).

What is a care pathway?

A care pathway is a well-regulated multidisciplinary care plan that illustrates the essential steps in the management of patients with a specific clinical issue. “A care pathway is a vehicle that facilitates standardisation of care and reduces unintended variability of care,” - said Michael Porter

There are two dimensions to a care pathway: horizontal and vertical

Horizontal dimension

The horizontal dimension is the expected duration of care pathways. To be effective, care pathways must expand beyond traditional health care silos to contain every care provider involved in the patient journey.

Vertical dimension

Whereas the horizontal dimension indicates the beginning and end of a care pathway, the vertical dimension enumerates the actors or roles active in the care process. Furthermore, each pathway must likewise integrate each healthcare professional active in the care pathway.

I-2.2.2.2 VBHC Agenda step 2 - Quantify outcomes and costs

I-2.2.2.2-A Introduction

Today, all healthcare systems are constrained by readjusting the rising cost pressures combined with new technological developments, more and more complex patients with multiple chronic conditions, elevated public conjectures and the progression of clinical practice. That is why, health systems must employ the resources they have judiciously and efficiently (32). Value-based health systems are therefore seen as an innovative system that could turn the quality of healthcare better for patients, while turning healthcare more cost-effective. Nevertheless, what a patient analyses as valuable may not be the same as what a physician views valuable.

Porter and Teisberg advise moving from an activity focus to an outcome focus. This model promotes the integration of health and care, so patient value must deal with outcomes measured by all providers across a full cycle of care. Thus, VBHC emerges as a supply-driven Healthcare system. Rather than estimating health outcomes by volume of services delivered (e.g. number of surgeries...), these are measured by end patient health outcomes: measured clinical outcomes and likewise outcomes that are distinguished by patients (so-called patient-reported outcomes : PROs) (Figure 5).

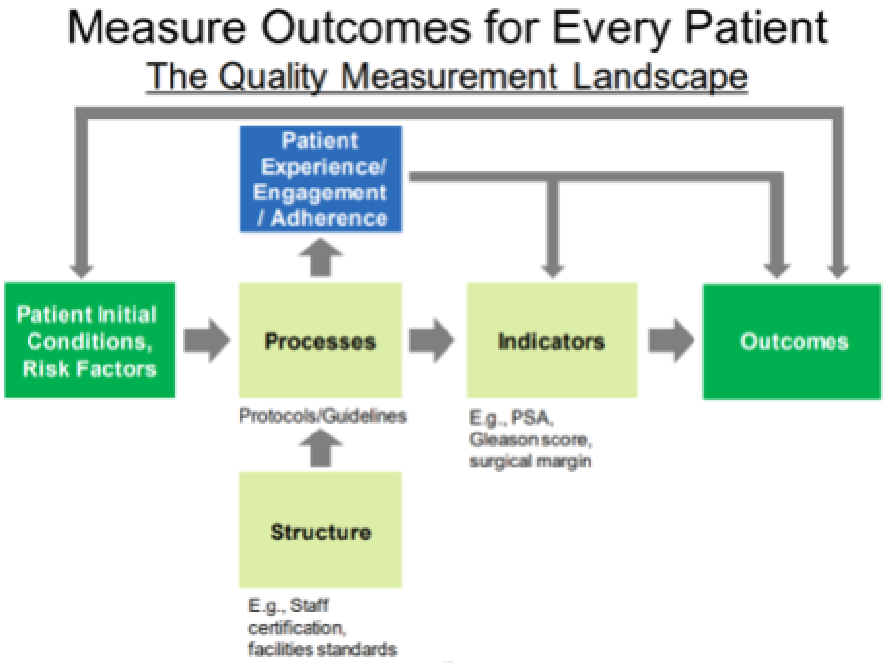


Figure 5: Measure Outcomes for Every Patient
Copyright 2019 © Professor Michael E. Porter

The entire paradigm strengthens a patient-centric approach to health care, which would replace facility-based payment systems, and support fragmentation of care delivery, with integrated care reimbursement models.

ICHOM was conceived to standardize the collection of outcomes to advocate VBHC changes. They advise pathways centred on the measurement of clinical and patient-reported outcomes in a standardised approach.

The OECD also takes a stand in the context of VBHC, highlighting the problem of wasting and the need for people-centred health systems that promote high-value care. As Secretary General Angel Gurría affirmed, during the 2017 Health Ministerial meeting on the theme: The Next Generation of Health Reforms, putting people at the centre demands “asking patients to identify outcomes that matter to them, such as their quality of life and functionality after medical care”. The OECD is establishing a Patient-Reported Indicators Survey (PaRIS) (33) with the goal of putting out internationally comparable indicators of patient-reported experiences and outcomes. These results will disclose the real value of healthcare spending, engaged on patients with one or more chronic conditions, who reside in the community and are predominantly treated in primary care or other ambulatory care settings.

I-2.2.2.2-B The Voice of the Patient

A patient or an individual person is holistically a human being with a continuity of life, such as healthy, at risk of disease or with a diagnosed condition, and a unique person with its own beliefs and behaviours.

Patient-centered definitions to increase value in healthcare

From the patient's point of view about delivering high value, the healthcare system must move from a "disease-centred" approach to a "person-centred" approach, where patients are equal partners and active in their care. Care at all levels must be guided by patient needs, goals, priorities and preferences. It should start with making sure that not only patient needs push research and development (R&D) of innovative therapies, but also by integrating patient-centred practices at the clinical and organisational levels and in governance. A compilation of evidence exists (34) on the primary role of patients in determining what value really means in VBHC, bringing their individual experiential understanding and expertise gained from disease. For a patient, healthcare innovation is not just about new treatments, but also about better treatments and quality of life.

But much of resources spent in research can be categorized as waste (35). Research almost never focuses on patient-identified priorities or does not frequently insert patient-meaningful outcome and quality of life measures (36). Moreover, The Patient and Consumer Working Party at the European Medicines Agency (EMA) wrote a discussion paper on valuing the patient perspective in the regulatory process. This document aims to provide more precision on how to augment both the quantity and the quality of the patient's input. Empowered and active patients are not consequently "cost drivers". When patients are supplied with complete insight and a collection of choices, they always choose the least invasive and intensive alternatives (37). Nevertheless, a 2018 study on patient commitment in clinical research evaluated that the return on value of patient involvement can basically overcome the initial investment (38).

Measuring what matters

“What can be counted, counts” (39) and “what gets measured, gets done” (40), therefore, identifying the right outcome measures is essential to assess healthcare performance, thinking about what outcomes patients judge as more important. Patient experience cannot be totally caught by metrics and necessitates acute exploration using interactive tools, based on real engagement with patients. Patient stories can be a very useful tool. In the UK, National Voices has worked out a “narrative on person-centred, integrated care”. These stories report what “good” looks like through a patient’s eyes and can help design suitable action (41). Some pioneering study has analysed the role of patients and their delegate organizations in health system renewal, providing to the adaptation to patient VBHC. The Empathy study (42) emphasised the role of patient empowerment, both individually and collectively, in appreciating and including the patient’s point of view and voice.

What do patient values and preferences mean?

Patient expectancies and choices are coming under intense analysis as the medical community and policymakers become aware of that. And they also understand that today patient expectations and preferences correlated with treatment outcomes, time spent, and greater appreciation for the delivered care: patient-centred care based on scientific evidence (43-45). Patient-reported outcome measures (PROMs) are collected typically with questionnaires to determine details of patients’ experience such as symptom burden, functional status, psychological and emotional well-being (46). In clinical practice, PROMs can be used to support communication between patients and clinicians, to aid in the discovery and handling of treatment toxicities and illness development or reappearance and ease the most favourable delivery of supportive care (47).

I-2.2.2.2-C Quality indicators in Europe

Worldwide, a mix of increasing costs, less access to quality medical care, and a deficiency of transparency and coordination to improve effective treatments delivery have been afflicting health systems. Porter and Teisberg maintain that fee-for-service was not established on ameliorating long-term patient outcomes, but on short-term cost-cutting cycles that aimed at clinical absence (5). Indeed, most health financing systems were created after the Second World War. The absence of standardization in evaluating improved chronic patient outcomes has conducted to poor transparency in benchmarking treatment performance and the dissemination of non-evidence-based treatment-related data and practices.

Outcomes

A distinction is made between PROMs (Patient Reported Outcome Measures), outcome indicators measured by patients, and CROMs (Clinician Reported Outcome Measures), outcome indicators measured by physicians. Results indicators are the only types of quality indicators that can be used to measure the medical service provided to the patient following medical treatment, in terms of clinical results (CROM) and quality of life (PROM).

PROMs

PROMs are quality indicators that measure the patient’s quality of life before or after medical or surgical treatment. The use of quality-of-life data makes it possible to assess the impact of one’s disease on different dimensions:

- Physical activity, such as the move around, perform household chores
- Psychological aspect, such as the presence of depression, anxiety, stress
- Social life, such as an impact on relationships with family, friends
- Taking into accounts its symptoms and their intensity such as pain, fatigue, loss of appetite, sleep disorders

PREMs

PREMs (Patient-Reported Experience Measures) focus on how the patient experienced care after hospitalization or consultation. These indicators take into account the opinion of patients on the basis of several factors such as the reception within the establishment, the clarity and exhaustiveness of the medical insight delivered by the caregivers, the quality of the meals, the comfort of the room...

ICHOM

The International Consortium for Health Outcomes Measurement (ICHOM) (48) initiative is a non-profit non-governmental organisation (NGO) created in the United Staes in 2012 at the initiative of four leaders: Michaël Porter (Harvard Business School), Dr. Stefan Larsson (Boston Consulting Group), Pr. Martin Ingvar (Karolinska Institute) et Pr. Donald Berwick (ex-Institute of Healthcare Improvement). ICHOM develops standardized patient indicators by pathology and at the global level with the aim of global comparability. ICHOM takes up the concept of value in health or VBHC, which consists of favouring quality indicators based on the results relevant to patients: the measurement of the quality of life of the patient and the evolution of his functional abilities, whether in the context of the management of a chronic disease or an acute episode. Other work on health value, relating to the transformation of health systems, has also been carried out by the World Economic Forum and the management consulting firm Boston Consulting Group (BCG) (49-51). ICHOM is based on a principle of transparency. The existing indicators are published by pathology online free of charge on a website accessible to all: www.ichom.org. Average response rates to ICHOM indicators are over 80% demonstrating the importance of patient outcome indicators. The ICHOM initiative is also supported by international organisations such as the Organisation for Economic Cooperation and Development (OECD). The international comparability of quality indicators is a major topic in the choice of their implementation. Therefore, it is essential to take into account the most relevant initiatives and reflections that already exist in other countries or at the international level such as ICHOM or OCDE with PaRIS (33). As part of this initiative, the objective set by the Ministers of Health of OCDE member countries is to develop common and comparable PROM-type results indicators within the Organization in order to make health systems more patient-centred through systematic measurement of patient quality of life markers.

The project of the French Plan Ma Santé 2022 is to “insert quality and relevance at the heart of organizations and practices” (52). This project indicates in particular that indicators developed in France will be designed based on a base of PROMs indicators retained within the framework of the PaRIS program, in a logic of international comparison of patient care methods.

I-2.2.2.2-D TDABC

Delivering health care that achieves strong patient outcomes at sustainable costs is a worldwide challenge. Amplified spending does not automatically convert into better patient outcomes. Moreover, there is large variation in health care outcomes both within and between health systems.

Costs are not measured well in healthcare at the specific medical condition level. Obviously, hospitals know how much they are spending. They can trace the spending to departments. But they cannot take the cost at the patient level. The approach TDABC enables that assignment of expenses to be done well at the patient level. It deals with two estimates: 1) understand clinical pathway that it used to treat a patient with a medical condition (who is doing each process step?). 2) How many minutes per year are then calculated for a person or piece of equipment to treat a patient. Then is calculated a cost per minute for an individual. It enables to make the payment contingent on delivering good outcomes, with value: Patient health outcomes per dollar spent.

Meliorating the financial management of healthcare organizations puts a considerable challenge as they function in a complex made up of many devices, involving healthcare, social factors, multiple clients, research and teaching (53). The numerous stakeholders involving patients, family members, and healthcare providers, requires organizational systems that can efficiently puck up beneficial information for decision-making (54). It is therefore headmost to meliorate the financial management performance of hospitals and set approaches to better manage this complicated environment in the ongoing economic scenario directed by costs restrictions and high standards of quality of care (55, 56)

The assessments involve classifying the direct and indirect costs. A precise estimation of costs is fundamental to conclude the effectiveness of an economic analysis in the decision-making procedure. This area of research uses economic valuation methods to determine the value of healthcare products and services by comparing costs and outcomes. Even though the relevance of accurate costing of healthcare services (54) has been extensively admitted, its application has been a defiance in practice due to an absence of cost standard calculation. In recent years, researchers have investigated systems that can help establish health care costs based on specific treatments or medicines, such as activity-based costing (ABC) and time-based costing (TDABC) (57). ABC is a costing method defined by Cooper and Kaplan (58) which pretends that various products use the same activities and that these activities necessitate healthcare resources in miscellaneous proportions. The ABC method gives a more precise evaluation of the cost of a product or service, particularly when it is constituted by a part of people-oriented activities and hospital environment.

TDABC (59) is a new version of ABC that does not need interviews with employees of organisations to assign costs to activities, as it straight allocates resource costs from cost objects via a simple formula: the hour cost rate. The core rule of this methodology is that it transforms cost factors into time equations, which show the time needed to accomplish a given activity. ABC and TDABC can precisely tie-in cost and activity because they both specify true cost estimations, particularly when the micro-cost approach is applied. In 2011, Professor Kaplan and Professor Porter issued the paper “The Big Idea: How to solve the Cost Crisis in Health Care” (60) and described how to employ TDABC. Professor Kaplan presented the TDABC as an analytical system designed to specify cost estimation across the entire cycle of care with great subjectivity.

Time-Driven Activity-Based Costing explained

The first phase in carrying out TDABC is to establish process maps for the entire cycle of care, containing all procedures from the first consultation to the last follow-up visit. This map combines both clinical and administrative steps and all the resources needed at each step, such as personnel, equipment, consumables and supplies. To fill out the process map, the time must be evaluated or calculated for each resource used at each stage of the process for a patient. After, the capacity cost rate must be calculated for each resource: all associated costs are divided by the available capacity (excluding breaks, meetings, education etc) of each for the treatment of patients. In the end, patient-level care costs can be evaluated by multiplying the capacity cost rate by the time resources have been consumed for each patient’s care cycle.

Advantages of TDABC

TDABC can reduce costs by reconstructing processes to decrease steps that do not provide to meliorate patient outcomes and to cut down downtime. It supplies information on how to enhance processes over a full cycle of care and how to let clinicians perform at the “top of their license”.

Nowadays, US health care costs outpace 17% of GDP and keep on rising. Worldwide, countries allocate less of their GDP on health care, but have the identical ascending tendency. The ageing population and the progress of innovative treatments are the roots of part of this growth. However, some experts recognize a more basic source of rising costs, such as the system by which those costs are calculated. Rather than concentrating on the costs of treating individual patients with specific medical conditions during their care cycle, providers assemble and analyse costs at the speciality service level. The cure for the cost crisis does not need medical scientific improvements or new government rules. It just requires a new approach to precisely measure costs and correlate them to outcomes.

I-2.2.2.3 VBHC Agenda step 3 – Bundled payment – VBHC reimbursement

I-2.2.2.3-A Bundled Payments

Bundled payment consists of defining **a single price** for **each medical condition**, containing all medical consultations and examinations necessary for proper care. This is not just the cost of an individual service, but also the total cost of all services needed to treat a precise medical condition. To maximize patient value, a bundled payment should comprehend the whole cycle of care necessitated to treat a medical condition. It must warn results, such as return to normal function, reduction of pain or aggravations. It should be adjusted to the risk likely to alter the patient’s state of health. It should provide an equitable profit by including a margin over the entire costs for an effective care. A bundled payment should include a warning to limit the care provider’s exposure to abnormally high costs resulting from disastrous or outlier cases.

Fee-for-service

Fee-for-service is a payment method where health services are unbundled and paid by unit. That is the payer reimburses based on the treatment delivered. This practice of fee-for-service is usually denounced because it can stimulate physicians to over-treat patients, and so, to motivate demand. An issue of this method of payment is the absence of cost control. In accordance with Porter and Kaplan (2016) (61), fee-for-service trumps quantity over quality, which is a barrier to meliorating the quality of health care delivery.

Payment per case (Diagnosis-related group)

This method segregates patients conforming to their diagnosis. Patients belonging to the identical group are assumed to have analogous treatment, thus showing a similar clinical course. In such a way, the costs should not vary greatly between patient groups, as it includes all costs from the time of admission to the time of discharge. But it has been argued that this could prompt hospitals to multiply the number of patients or discharge patients too soon.

Capitation

Care providers collect a fixed sum of money for each patient or group of patients designated to them, for a period, whether or not that person undertakes care (Berwick - 2016) (62). Payment is made antecedentally. Hence, it is established on the forecast average healthcare use of this patient group, with patient payment mainly differing by age and health status. Capitation can be applied to approximately any medical condition, from primary care to surgery. Capitation obligates a sharing of risk between the payer and the health care provider. Thus, hospitals will be encouraged to reduce costs. Porter and Kaplan (2016) (61) denounce this system as it may produce competition in costs, rather than appropriate patient outcomes.

Bundle Payment

Based on payment systems adopted in other sectors, bundled payment reposes on paying, at the time of admission, the total cost of treatment, for the entire care cycle. It can be seen as an intermediate option between fee-for-service and capitation, as the risk is shared between payers and providers. The principal distinction between this bundled payment and capitation is that payment is dependent on achieving patient-relevant outcomes and exclusively contains treatments that are related to the medical condition (Porter and Kaplan – 2016) (61). First of all, bundled payment implementation needs to measure the outcomes that matter most to patients (clinical and patient-related outcomes). Afterward, it is essential to precisely outline the journey that the patient makes with the accurate cost of each activity. In the end of bundled payment, different levels of care can be integrated, which signifies that various specialists or even establishments can be included in the care delivery.

I-2.2.2.3-B VALUE-BASED REIMBURSEMENT

A shift from fee-for-service to value-based reimbursement is required to line up the business model with delivery practice, in such manner providers are remunerated for value rather than volume of services. In accordance with the VBHC plan, bundled payment by requirement is the chosen payment model to improve value. Bundled payments are correlated to risk with providers for all services over a full cycle of care or a determined period of time. Providers are held accountable by payers to a set of outcome measures to ensure the quality of care for each bundled condition. And they can also be rewarded with bonus payments if the objectives are achieved.

Reimbursing care: Bundle Payments

The perfect bundle payment fills in for the cost of all care necessitated to treat a patient’s medical condition. In the situation of chronic diseases, the bundle can be conceived to fill in for all care for a period, for example one year. A crucial feature is that the bundle requires to be contingent on outcomes, if not the bundle might boost cost cut in disregard of the outcomes reached. Risk adjustment according to the patient’s situation and comorbidities is another important element.

I-2.2.2.4 VBHC Agenda step 4 - Integrated Care Delivery

Systems integration enables IPUs to provide the right care in the right place by the right provider within a multi-site care delivery system, which is one of the virtuous effects of the VBHC's agenda. Integrated systems permit systems to centralize volume on limited sites. This can conduce to greater value for patients through improved quality of treatment and reduced costs. For example, complicated breast cancer surgery can be realized at academic centres whereas follow-up assessments can be done at regional outpatient facilities.

I-2.2.2.5 VBHC Agenda step 5 – Expand VBHC Geography of care

A crucial step of VBHC's agenda is geography of care. This aims at developing centres of excellence that are experts of caring highly complex patients. The strategy of these Centres of Excellence is to collaborate with smaller hospitals to rethink how and where diverse activities are carried out in the best achievable approach.

I-2.2.2.6 VBHC Agenda step 6 – IT supporting VBHC

Elaborated information technology (IT) is required to administer value-based health care across various settings and providers. An IT platform should have the following characteristics, in accordance with the VBHC core concepts. Data should be patient-centred through facilities, sites, and time during the whole care cycle. IT platform uses the medical record accessible among the involved providers and patients. IT platform also enables effortless extractions of outcomes and costing measures by patient and medical condition, including templates and expert systems for each medical condition. IT platform proposes interoperability with various provider and payer organizations.

I-2.2.3 Transparency and Benchmarks

Providers are under increasing demand to benchmark their performance against other providers to show their value, which necessitates data transparency (63). From VBHC's perspective, however, the aim of open benchmarks is to blame poor performers, but to concentrate on lessons that can be learned from high performers. Outcome based benchmarks are handled internally, between team members, and externally, across various teams and providers. Then, all players must be coordinated to a common risk-adjusted scorecard. This is a crucial requirement to keep from adverse patient selection and guarantee statistically comparable outcomes.

Since a hospital can outperform or underperform depending on the specific condition measured, this portal does not directly compare hospitals, but rather hospital medical teams. This innovative achievement is a pace towards empowering users of the health system to make informed decisions about where to get care. Medical teams are stimulated by public data outcome to enhance their value in order to captivate more patients, keep staff talent and bargain health plans with payers (64).

Various pioneering eagernesses are being worked out across Europe to benchmark outcome data. The European University Hospital Alliance (EUHA) was established in 2017 with the engagement of nine of the most giant university hospitals to convert their organizations into a value-driven model. Priority fields for the Alliance are moving towards more person-centred care, as well as measuring outcomes that matter to patients. Therefore, a committed working group uses in common best practices and compares results for a select number of patient journeys. This assignment targets to set up a shared data platform to ease knowledge exchange and enhance patient outcomes and experience (65). Global collaborations among health systems are as well ongoing. The Nordic Interoperability Project focuses to reach, swap and compare health data between Scandinavian countries (66)

Carrying out open, value-driven repositories necessitates shared metrics, nominative comparisons and comprehensible outcome data and finally an autonomous body to conduce operations in a neutral way (67)

I-2.2.4 VBHC in Europe

Efficiency in healthcare has usually been defined as cost cuts. However, in recent times in developed economies, healthcare policymakers have understood the idea of value in accordance with the compliance of health systems or health providers to pursue highest clinical practice. Progressively, physicians are advocating patient-centricity focussed on value, as promoted by Porter and Teisberg (2006) (5) who defined "value-based healthcare" in determining outcomes of health treatment related to cost.

Solidarity is strongly established in Europe with universal healthcare defined by Article 35 of the Charter of Fundamental Rights of the European Union. The European concept of solidarity reminds the importance of access, equity, quality, performance, efficiency and productivity. Health can be defined as an intrinsic value, a prerequisite to get a "good life". At European population level, universal healthcare expects to provide equitable health. The Expert Panel on Effective Ways of Investing in Health (EXPH) highlights that the notion of "value-based healthcare" appears more convenient in carrying out the guiding basis of solidarity-based healthcare systems. Wales started in value-based healthcare by defining value and making investment decisions in cataract surgeries. (68)

In 2017, some practices in England, Wales, Italy and Scotland conducted to the concept of value-based healthcare (VBHC) with 3 descriptive facets of value (personal value, allocative or populational value and utilisation value). The Royal College of Physicians of the United Kingdom (69) the Berlin Chamber of Physicians (70) and the Istituto Superiore Sanita in Italy examined and admitted this more complete definition of VBHC.

The UK and Italy (71) agreed to approve these three different characteristics of value, named the "**Triple Value**" Model: 1 – The **personal value** means that one person gets suitable care driven by outcomes of patient' value; 2 – **The allocative value** ensures equitable distribution of resources among the population avoiding "inequity by disease" ; 3 – **The technical value or utilisation value** is relative to obtaining the best outcomes, results with available resources and equitable access. Thus, the "Triple Value" also includes the needs to identify and minimize inequalities.

I-2.3 Breast Cancer Care

1-2.3.1 Introduction of Breast Cancer Care

Cancer Care

Cancer burden goes on increasing due to ageing and population growing, in conjunction with changing lifestyles and cancer risk factor exposure (72). In 2017, the World Health Assembly adopted the Resolution Cancer prevention and control in the context of an integrated approach (WHA10.12) (73) which exhorts governments and WHO to quicken action to reach the goals indicated in the Global Action Plan for Cancer Prevention and Control of NCDs 2013-2020 (74) and the United Nations 2030 Agenda for Sustainable Development (75) to decrease premature mortality from cancer.

Despite an increase in cancer incidence, deaths from cancer have declined in the last years. Death rates from cancer declined by 23% in the United States over the last 20 years. In developing countries, cancer deaths have also declined due to several factors, including early diagnosis, improved diagnostic approaches, new cancer treatments, and lifestyle changes (76, 77).

In 2020, 2.3 million women were diagnosed with breast cancer and 685,000 deaths worldwide. By the end of 2020, 7.8 million women alive had been diagnosed with breast cancer in the past 5 years, turning it the most prevalent cancer in the world. There are more disability-adjusted life years (DALYs) lost by women from breast cancer worldwide than from any other type of cancer. Breast cancer happens in all countries of the world in women at any age after puberty, but with growing rates later in life.

Breast cancer mortality did not really vary from the 1930s to the 1970s. In the 1980s, ameliorations in survival began in regions with advanced diagnosis programs associated with various modes of treatment to annihilate invasive disease.

Access to Care

Patient access to oncology medicines differs extensively across countries, and closer examination is being made on value by payers and patients, who may come up against an increasing share of treatment costs. As patient costs increase faster than incomes, the number of patients who actually have access to new drugs is gradually diminishing. In some extreme measure, these patients are carrying out difficult choices between nonmedical costs and healthcare costs, and at the most disastrous, giving up life-saving treatment because of the costs, presuming their access to care was not previously restricted by the settlements of payer and provider.

Today, breast cancer is the most diagnosed cancer in women, and it is the most common cancer in the world and the first cause of cancer death in women (78). The last 20 years have seen enormous scientific progress. Understanding of the role of genetics, genomics and gender differences in cancer has improved dramatically, as has digitization and the growing power of computer-based analytical tools.

Ensuring high standards in cancer care

The European Beating Cancer Plan aims to guarantee that EU citizens have the right to access affordable, preventive and healing healthcare of great quality, as required by the European Pillar of Social Rights (79).

The European Society of Breast Cancer Specialists (EUSOMA) intends to coordinate the management of breast cancer in Europe, to promote the establishment of certified Breast Centres and to meliorate quality control. Subsequently, the first European Breast Cancer Conference, EUSOMA established the conditions for a specialist breast centre in 2000 (80), and these requirements are frequently revised (81)

Who is at risk?

Breast cancer is not a communicable or infectious disease. Contrary to some cancers that are due to infection causes, like human papillomavirus (HPV) infection and cervical cancer, there are no established viral or bacterial infections related to the ongoing of the breast cancer. About half of breast cancers expand in women who have no identifiable breast cancer risk factors other than gender (female) and age (over 40). Some factors augment the risk of breast cancer, such as advanced age, obesity, harmful use of alcohol, family history of breast cancer, history of radiation exposure, reproductive history (like age at which menstruation began and age at first pregnancy), smoking and post-menopausal hormone therapy. However, even if all the conceivably alterable risk factors could be handled, it would hardly decrease the risk of suffering from breast cancer by at most 30%. Female sex is the most significant risk factor for breast cancer. About 0.5 to 1% of breast cancers appear in men. Breast cancer treatment for men pursues the same rules of management as in women. A family history of breast cancer intensifies the risk of breast cancer, but most women diagnosed with breast cancer have no identified family history of the disease. Some inherited “high penetrance” gene mutations actually reinforce the risk of breast cancer, the most predominant being mutations in genes BRCA1, BRCA2 and PALB-2 (82). Women with mutations in these crucial genes might look at risk reduction strategies such as surgical removal of both breasts. This highly invasive surgery exclusively involves a very restrictive number of women.

Global impact

Age-standardized breast cancer mortality in high-income countries fell by 40% between the 1980s and 2020. Countries that have been successful in decreasing breast cancer mortality have been able to reach an annual reduction in breast cancer mortality of 2-4% per year (83). If an annual mortality diminution of 2.5% per year happens worldwide, 2.5 million breast cancer deaths would be averted between 2020 and 2040. Strategies to meliorate breast cancer outcomes rely on basically reinforcing the health system to deliver treatments that are known then to work (84).

WHO response

WHO’s Global Breast Cancer Initiative (GBCI) aims to diminish breast cancer mortality worldwide by 2.5% per year, avoiding 2.5 millions breast cancer deaths in the world between 2020 and 2040 (85). Decreasing global breast cancer mortality by 2.5% per year would prevent 25% of breast cancer deaths by 2030 and 40% by 2040 in women under 70. The three pillars to reach these goals are: health promotion for early detection; timely diagnosis; and comprehensive management of breast cancer.

Europe Cancer

The European Cancer Information System is included in the Knowledge Centre on Cancer (86), an important initiative of The European' Beating Cancer Plan. With a budget of 4 billion euros, the Plan targets cancer in an integrated approach, mainstreaming health in all policies and multi-stakeholder. Furthermore, by advocating of precise and state-of-the-art knowledge on cancer, the Knowledge Centre also contributes to the Horizon Europe Mission on cancer (87) to reach by 2030 more than 3 million lives saved, living better and longer.

The JRC serves the European Network of Cancer Registries, the International agency for Research on Cancer (IARC) (88), EUROCARE (89) and other international institutions and projects to supply the latest data on indicators that evaluate the burden of cancer in Europe. The indicators contain annual estimates of 40 countries, covering all EU Member States. The goal is to sustain research and decision-making in public health, besides to be a source of information for European citizens.

I-2.3.2 Breast Cancer Epidemiology

Breast cancer develops in the lining cells (epithelium) of ducts (85%) or lobules (15%) in the glandular tissue of the breast. At first, the cancerous growth is enclosed in the duct or lobule ("in situ") where it frequently creates no symptoms and has minimal potentiality to disperse (metastasis). As things progress, these cancers in situ (stage 0) can advance and occupy the surrounding breast tissue (invasive breast cancer) and then spread to adjoining lymph nodes (regional metastasis) or to other organs of the body (distant metastasis). When a woman dies from breast cancer, it is due to widespread metastasis (90).

Breast cancer treatment can be very effective, particularly when the disease is diagnosed early (91). Treatment for breast cancer usually resides of an association of surgical removal, radiation therapy, and drugs (hormonone therapy, chemotherapy and/or targeted biological therapy) to handle the microscopic cancer that has expanded from the breast tumour through the blood (92). Such treatment, which can avoid the growth and spread of cancer, thus saves lives.

Signs and symptoms

Seeing a doctor at the first sign of a possible symptom permits for more successful treatment (93). Typically, symptoms of breast cancer involve: a breast lump or thickening; size change, shape of breast, dimpling; redness, pitting or other alteration in the skin; alteration in nipple aspect or in the skin surrounding the areola; uncommon nipple excretion (94).

Breast cancers can disperse to other parts of the body and bring about other symptoms (95). Frequently, the most usual first perceptible site of spread is the lymph nodes under the arm, even though it is feasible to have cancer-bearing lymph nodes that cannot be noticed. As things progress, cancer cells can expand to other organs, such as the lungs, liver, brain, and bones. When they already extend to these sites, new cancer-related symptoms like bone pain or headaches may emerge.

Breast Cancer Diagnosis

Breast cancer treatment can be successful, reaching survival probabilities of 90% or more, especially when the disease is diagnosed early (96). Treatment usually lies on surgery and radiation therapy for disease control in the breast, lymph nodes and surrounding areas, systematic therapy to treat and decrease the risk of cancer spreading with metastasis. Cancer drugs include hormone therapy, chemotherapy, and in some cases, targeted biological therapy (antibody) (97).

Today, breast cancer check-up involves an association of clinical examination, imaging, cytopathological and histopathological evaluation (98). Most early breast cancer are without any symptom. Breast cancer is often first discovered on a mammogram. In the event of a touchable mass or indicative lesion on a mammogram, a breast ultrasound is accomplished, sometimes with a biopsy, to achieve the diagnosis. Additional imaging can be carried out, if necessary. When chemotherapy is supplied before surgery, tumour response is assessed using breast MRI.

Primary care physicians

Primary care physicians (PCPs) execute a crucial role in the care and management of breast cancer patients in any context. The PCP is frequently the first physician concerned in the process of diagnosing breast cancer. The cancer may be diagnoses during an ordinary screening mammogram, or the patient may request the recommendation of her PCP for a self-detected abnormality in her breast. The PCP will then indicate the patient to a radiologist, a breast surgeon or a breast centre for a more in-depth diagnosis and an accurate treatment plan. During active breast cancer management, the patient will keep on seeing her PCP. PCP plays a crucial role in the management of breast cancer patients at all steps of the disease: prediagnosis, diagnosis, during treatment, after treatment survivorship care, care for elderly patients, and care for terminally patients (120)

I-2.3.3 Breast Cancer Treatments

In the past, all breast cancers were treated surgically by mastectomy (complete removal of the breast) (99). Mastectomy may still be necessary, when cancers are large. Now-a-days, the greater number of breast cancers can be treated with a smaller surgery called a “lumpectomy” or partial mastectomy (100), in which just the tumour is taken out from the breast. In these situations, radiation therapy to the breast is often required to diminish the chance of a recurrence in the breast (101).

Proper diagnosis of cancer for suitable and effective treatment, as each type of cancer requires a precise treatment plan. Treatment regularly includes surgery, radiotherapy and or systematic therapy (chemotherapy, hormonal treatments, targeted biological therapies, immunotherapy) (102). Appropriate selection of a treatment regimen considers both the cancer and the person being treated. Accomplishment of the treatment protocol within a delimited period is imperative to accomplish the predetermined therapeutic result. Deciding treatment aims is an essential first step. The first target is always to cure cancer or essentially extend life. Enhancing the patient's quality of life is still a crucial purpose (103). This can be accomplished with support for the physical, psychosocial and spiritual well-being of the patient and palliative care in terminal stages of cancer (104). Some common types of cancer, like breast cancers have high chances of being cured when detected early and treated according to best practices (105).

Breast Cancer surgery

Surgical removal of the tumour is the keystone of early-stage breast cancer treatment (106). For breast surgery there are two options: a mastectomy involving removal of the entire breast and BCS concerning only the tumour and a tiny volume of surrounding normal tissue. Moreover, BCS associated to radiation therapy is called breast-conserving therapy (107), or BCT. Most women with invasive cancer will undergo a surgery to estimate the presence of cancerous cells in the axillary lymph nodes (108). Lymph nodes are pulled out at the time of cancer surgery for invasive cancers. In the past, complete removal of the lymph node bed under the arm (complete axillary dissection) was considered fundamental to avoid the spread of cancer. A smaller lymph node procedure called a "sentinel node biopsy" (109) is today chosen because it causes fewer complications. It utilizes a dye and/or radioactive tracer to locate the first lymph nodes to which cancer might spread from the breast (110).

Medical treatments for breast cancer, which can be administered before ("neoadjuvant") (111) or after surgery ("adjuvant"), are established on the biological subtyping of the cancers. Cancers that reveal the estrogen receptor (ER) and/or the progesterone receptor (PR) are probable to respond to endocrine (hormone) treatments (112). Cancers that do not indicate ER and PR are “hormone receptor negative” and should be treated with chemotherapy, except if the cancer is very small.

Systemic therapy

Systematic breast treatment is characterized as the administration of drugs that circulate throughout the body, such as cytotoxic chemotherapy, hormone therapy, targeted therapy, and more freshly, immunotherapy (113). Chemotherapy regimens applicable today are very successful in reducing the chances of the cancer spreading or reappearing and are generally prescribed as outpatient treatment (114).

Radiation Therapy

Radiation Therapy (RT) is a keystone of treatment in post-lumpectomy breast and post-mastectomy settings (115). Postoperative RT is employed to cut down the likelihood of local-regional recurrences of breast cancer after surgery. Furthermore, RT diminishes the risk of recurrence, and the leading effect is seen for local and regional control.

Furthermore, radiation therapy plays a very outstanding role as well in the treatment of breast cancer (116). For early-stage breast cancers, radiation therapy can keep a woman from having to endure a mastectomy. With later stage cancers, radiation therapy can minimize the risk of the cancer recurring even after a mastectomy. And with advanced stage of breast cancer, radiation therapy can decrease the probability of death from breast cancer.

Palliative care

Palliative care is a treatment aimed at alleviating, rather than curing, the symptoms and suffering caused by cancer and enhancing the quality of life of patients and their families (117). Palliative care can improve people’s life, turning it more comfortable. It is especially required in locations with a high proportion of patients with advanced stages of cancer where a little chance of recovery still exists. Alleviation from physical, psychosocial problems through palliative care is achievable for more than 90% of patients with advanced cancer. Competent public health strategies, involving community and home care, are crucial to supporting pain relief and palliative care to patients and their families.

Palliative care and end-of-life care

Conforming to the World Health Organization (WHO), palliative care (PC) is a concept that ameliorates the quality of life of patients and their families confronted with the problem related to a life-threatening illness, through the prevention and alleviation of suffering through anticipatory diagnosis and accurate assessment and treatment of pain and other physical, psychological and spiritual issues (118). The “palliative” step of the disease mentions particularly goals of care excluding cure or prolongation of survival.

Psycho-Oncological and Survivorship

Cancer and its treatments have a considerable influence on the quality of life of patients, their families and caregivers. The success of breast cancer therapies relies upon the full duration of treatment. Partial treatment is less probable to get to a positive result (119).

I-2.3.4 Value-Based in Breast Cancer Care

The VBHC paradigm has been implemented in cancer care to enhance disease management, acknowledging epidemiological, medical, psychological and economic outcomes. Following the VBHC paradigm, various European hospitals have brought about some of its elements, while others are being developed. Actually, care delivery is frequently segmented, needing multiple departments and disconnected providers to manage the patient care process. Establishing committed facilities with dedicated teams and combining different clinical interventions for a specific disease into a single care pathway can supply greater patient care and cut down the burden of recovery, positively influencing the others measured outcomes (28).

As stated in the report of the World Health Organization (2016), cancer represents the second highest burden for patients in the European Union (121). In present-day, the global cancer burden has grown to 18.1 million cases and 9.6 million cancer deaths (122), compared to 2012 when global cancer statistics (GLOBOCAN, 2012) indicated: "an estimated 14.1 million new cancer cases and 8.2 million cancer deaths occurred in 2012 worldwide" (123). In 2018, the European Union supported a significant burden of the global cancer burden with nearly a quarter of evaluated cancer cases happening in this region.

As according to Porter's idea, Johansen and Saunders (2017) (124) examined the healthcare organizations implementing the VBHC paradigm. From these investigations, they built guidelines for implementing the theoretical paradigm in cancer care. The four fundamental phases in transitioning current cancer care to a value-based system are: 1) create for each type of cancer universal patient-reported outcomes (PROs) across the entire cycle of care, 2) Define specific multidisciplinary units to cancer, 3) set up a system that caught all data produced, and 4) Permanently enhance treatment strategies thanks to research. Therefore, VBHC has been implemented to examine particular cancer types and make better management decisions, integrating epidemiological, medical, psychological and economic outcomes. Picturing the full cycle of care for a particular disease permits stakeholders to distinguish all pertinent outcomes and their measurement (27).

The Martini-Klinik, a major German hospital, measured the functional and oncological outcomes of cancer patients after surgery. Patients were asked to fill out a questionnaire about their quality of life, urinary and sexual functioning at four different time points (miles): "1) prior to their surgery, 2) one week after surgery, 3) three months after surgery, and 4) one year after surgery" (125)

In 2012, the International Consortium for Health Outcomes Measurement (ICHOM) began building standard sets of outcomes for particular medical conditions. Today, cancers such as breast, prostate, colorectal and lung cancers have their own lists of standardized outcomes, measurement tools, time points and risk adjustment factors (126). Outcome measurement offers greater opportunities to comprehend if care is beneficial for patients and which treatments are the most effective for each medical condition. Furthermore, these data allowed seven Dutch hospitals to get a better understanding of expenditures and to foster a cost review. The Santeon Network reached reductions of 74% in the rate of reoperation due to complications in breast cancer patients and a cut of almost 30% in not required inpatient stays. The Santeon Network applied the value-based healthcare concepts among three different groups of cancer patients (breast, prostate and lung) by pursuing these steps: 1) set up a multidisciplinary team to create the measured outcomes, 2) internally achieve clinical knowledge to better manage the care cycle and approve new medical processes, 3) share knowledge externally to stimulate improvements, and 4) work with patients and payers to move to value-based contracts (127). In 2016, a German hospital implemented a digital system to measure the PROs of breast cancer patients using the Breast ICHOM dataset and obtained more than 2500 inquiries from 541 patients (128). The scientific literature demonstrates that installing e-health systems would augment data collection, cut data loss and decrease errors in the data entry process. Additionally, patients reported that they would be more serene utilizing electronic systems, compared to paper-and-pencil methods (129, 130).

Value-based healthcare and outcome measurement in Breast Cancer Care

An increasing prevalence of women with breast cancer come from both the increased incidence of breast cancer and the improved breast cancer survival rates. This poses additional challenges for the medical community, as breast cancer and its treatment can adversely alter the physical, psychological and social well-being of patients, both during and after treatment (131). A patient-specific should perfectly fit between patient and disease characteristics and suggested treatment strategy should be wanted, selecting the slightest invasive treatment achievable while keeping up excellent cancer control. Along these lines, over-processing, as well as under-processing, can be prevented.

In recent years, there has been a shift from a more generic care way to a more patient-centred approach to care (132). With patient-centred care, cancer care has turned into more targeted on the person needs of breast cancer patients, both clinically and in terms of personal values. This patient-centred delivery of care is the potential of the foundation of value-based healthcare (VBHC). VBHC focuses to improve the quality of care delivered by measuring and enhancing outcomes that indicate value rather than volume. Value of care is evaluated as health outcomes comparative to total costs (27). As the value of health care relies on the outcomes and not on the inputs, the value is assessed by the results obtained and not by the volume of services. Undeniably, these outcomes display patient-oriented outcomes instead of structure or process measures that do not consistently reveal patients' outcomes acquired. In VBHC, outcomes are patient-reported (PRO) and also provider-reported, such as breast cancer survival, complications and hospitalization rates (27).

For example, radiotherapy after BCS may show great clinical outcomes for locoregional control and breast cancer-free survival. But PROs may find that breast cancer patients do not comply to BCT due to adverse side effects, daily sessions of radiotherapy too intense, and may be a worst quality of life. The effectiveness of treatment consequently has various aspects, containing clinical effectiveness additionally of the benefit encountered by patients as a direct corollary of that particular therapeutic act (133). Especially in the care of patients with early-stage breast cancer, the prominence of value is more and more acknowledged. Given the outstanding and related oncological outcomes and various loco regional strategies applicable, all with distinct outcomes and costs, there is a growing need for outcome measures that precisely discriminate treatment strategies.

The results of the PROMs can be discussed at the outpatient clinic, at the same time as consultations, designing to discover latent health issues that may need special consideration. Otherwise, PROMs are besides appropriate for benchmarking, as regular PROMs assessments can indicate the day-to-day care delivered, producing an understanding of the effectiveness of care.

Overview of the care pathway in breast cancer care

The interdisciplinary care pathway for breast cancer systematically gets the outcomes. In addition to these sets of results, the pathway provides remote monitoring of patients for treatment side effects during systematic treatment and quickly after surgery. Personalized data for the patient is added during the whole of the care pathway based on their individual care pathway variant. Side effects are monitored using the article bank, containing physiological and psychological side effects. When thresholds are reached, advice on coping with side effects is transferred to the patient if low or mild severity cases, or the right member of the healthcare team in cases of moderate to high severity.

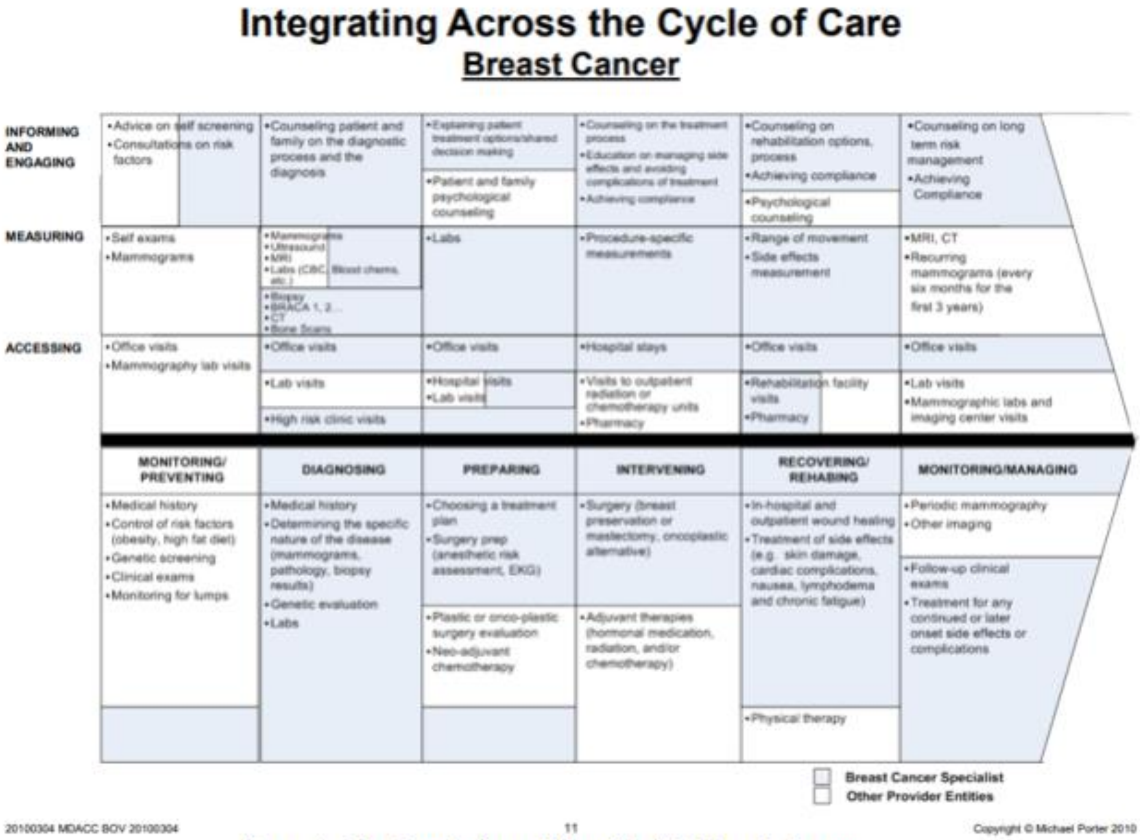
The pathway involves all treatment modalities such as chemotherapy, immunotherapy, radiotherapy, hormonal therapy, surgery and the main combined strategies (neoadjuvant and adjuvant treatment).

The breast cancer care pathway can be divided into 3 phases:

2. Baseline / choice of treatment
3. Acute treatment phase
4. Long-term follow-up post-treatment (annual survey for 10 years)

Benefits

The breast cancer care pathway grants numerous benefits that will augment efficiency and ameliorate the quality of care for the patient and caregivers, providers. It will reach it thanks to automatic data collection, automatic scoring calculations, less administrative burden for the care team, automatic alerts for the care team with alarming patient-reported outcomes, health literacy...



Integrating Across the Cycle of Care

Breast Cancer

	MONITORING/ PREVENTING	DIAGNOSING	PREPARING	INTERVENING	RECOVERING/ REHABING	MONITORING/MANAGING
INFORMING AND ENGAGING	•Advice on self screening •Consultations on risk factors	•Counseling patient and family on the diagnostic process and the diagnosis	•Explaining patient treatment options/shared decision making •Patient and family psychological counseling	•Counseling on the treatment process •Education on managing side effects and avoiding complications of treatment •Achieving compliance	•Counseling on rehabilitation options, process •Achieving compliance •Psychological counseling	•Counseling on long term risk management •Achieving Compliance
MEASURING	•Self exams •Mammograms	•Mammograms •Ultrasound •MRI •Labs (CBC, Blood chems, etc.) •Biopsy •BRACA 1, 2… •CT •Bone Scans	•Labs	•Procedure-specific measurements	•Range of movement •Side effects measurement	•MRI, CT •Recurring mammograms (every six months for the first 3 years)
ACCESSING	•Office visits •Mammography lab visits	•Office visits •Lab visits •High risk clinic visits	•Office visits •Hospital visits •Lab visits	•Hospital stays •Visits to outpatient radiation or chemotherapy units •Pharmacy	•Office visits •Rehabilitation facility visits •Pharmacy	•Office visits •Lab visits •Mammographic labs and imaging center visits
	MONITORING/ PREVENTING	**DIAGNOSING**	**PREPARING**	**INTERVENING**	**RECOVERING/ REHABING**	**MONITORING/MANAGING**
	•Medical history •Control of risk factors (obesity, high fat diet) •Genetic screening •Clinical exams •Monitoring for lumps	•Medical history •Determining the specific nature of the disease (mammograms, pathology, biopsy results) •Genetic evaluation •Labs	•Choosing a treatment plan •Surgery prep (anesthetic risk assessment, EKG) •Plastic or onco-plastic surgery evaluation •Neo-adjuvant chemotherapy	•Surgery (breast preservation or mastectomy, oncoplastic alternative) •Adjuvant therapies (hormonal medication, radiation, and/or chemotherapy)	•In-hospital and outpatient wound healing •Treatment of side effects (e.g. skin damage, cardiac complications, nausea, lymphodema and chronic fatigue) •Physical therapy	•Periodic mammography •Other imaging •Follow-up clinical exams •Treatment for any continued or later onset side effects or complications

☐ Breast Cancer Specialist
☐ Other Provider Entities

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figure 6 : The Care Delivery Value Chain in Breast Cancer.
The table has been taken by Porter 2010, What is value in health

Therefore, the hierarchy of outcome measures in breast cancer involves the collection of specific data for each level. As Porter and Tiesberg proposed (figure 6), Tier 1 deals with survival and degree of recovery. It contains survival rate, degree of remission, functional status, breast conservation, and depression. Tier 2 deals with time to recovery and disutility of care. It targets remission time and functional status, infections, nausea, suspension of treatment, treatment failures, limitation of movement, depression. In the end, Tier 3 refers with stability of recovery and long-term consequences. It rates cancer recurrence, durability of functional status, incidence of secondary cancers, brachial plexopathy, fertility, pregnancy complications and premature osteoporosis. In addition, risk factors and initial conditions must be taken into account to produce benchmark risk adjustment and to examine their consequences on all levels of the outcome hierarchy. Risk factors for patients with breast cancer may come from stage of disease, type of cancer, receptor status (positive or negative), sites of metastasis, former treatments, age, menopausal status, general health status, comprising comorbidities, and psychological and social factors.

PART II Research Methodology

Systematic review and qualitative content analysis

The exploration of this theme has resulted in an extensive but dispersed knowledge of the Value Agenda's elements. In different European countries, the transformation from financing by volume "Fee-for-service" to paying for value "bundled payment" has been moving slowly. The aim of the qualitative content analysis is to identify the missing steps "gap" of the value agenda as defined by Porter to achieve funding of breast cancer care based on the patients' value, by systematically collecting these steps already achieved in Europe.

Chapter II-1 Research aims and design

II-1.1 Introduction

The research question and the general objective of this work are presented as follows: describe and analyse the 6 steps of the value agenda achieved in Europe in Breast Cancer Care, the missing steps "gap" in the implementation of value-based interventions in breast cancer care in Europe to understand the level of implementation of bundled payment.

In order to achieve the general objective, the following specific objectives have been set:

1st goal: Identify completed steps for implementing value-based interventions in breast cancer care in Europe

2nd goal: Analyse the missing steps "gap" for setting up breast cancer care bundled payments in Europe thanks to value-based healthcare.

The approach of this study is qualitative and quatitative, through a systematic review of scientific articles. The systematic review focused on value-based healthcare in breast cancer care in Europe.

The documentary research consisted of collecting and analysing the existing literature on the subject under study. The search focused on a period that could encompass current relevant literature, with particular attention to scientific publications from 2012 to 2021. A comparison of the texts was carried out taking into account the perspectives (convergences, divergences and complementarities), contents (agreements, obvious disagreements and complementarities) and leads for the continuation of the research (134)

The systematic analysis focused on the value-based healthcare agenda in breast cancer care in Europe. The data collected was processed in a Qualitative Content Analysis following PRISMA methodology with Cochrane Covidence. This qualitative analysis helped us to quantify the occurrence of certain words dealing with the VBHC agenda.

II-1.2 The Qualitative Content Analysis

This content analysis is both quantitative (focused on counting and measuring) FREQUENCY and qualitative (focused on interpreting and understanding). To remain objective and minimize biases, we used: Autocoded by NVIVO version 11

- Words were the unit of meaning to be coded.
- With objective characteristics
- The text of the 179 scientific articles were coding with NVIVO version 11 according to the rules.
- The results were analysed and conclusions were drawn

It should be noted, from the outset, that the **qualitative content analysis** methodology was used, as a data structure, for the synthesis of the results of the research study conducted.

The Content analysis tool

The use of an analysis tool therefore aims to extract the researched from the literature, to stimulate the inductive process, to focus on the data without value judgments, watch out for rough diamonds. This allows the assignment of conceptual designations, even provisional ones, or the discovery of categories and their properties. But it should always be used flexibly, respecting what the data tells us, and as an extension of our own sensitive characteristics or abilities.

Open coding in vivo, axial and selective coding, theoretical coding

There are many ways to record theoretical concepts and ideas, and each researcher must discover which system works best for them. Charmaz (164) refers to targeted coding, which means using the first most significant and/or most frequent codes, to examine large volumes of data. This implies, according to the author, to decide which initial codes make the most analytical sense, arguing for an incisive and complete categorisation.

II-1.3 Qualitative Content Analysis of Value-Based Healthcare in Breast Cancer Care in Europe (2012-2021)

With this study, it was a question of identifying the different stages of the Value Agenda defined by Porter in the context of the treatment of Breast Cancer in Europe between 2012 and 2021 in order to conceptually synthesise the progress towards a new healthcare funding system from volume (Fee-for-Service) to Value (Bundled Payments) in this area.

Description of the method

The following keywords were used :Title-Abstract-Key ((((“value-based” OR ”value based” OR “vbhc” OR “vbcc” OR “high value care” OR “tdabc” OR “ PROM” OR “patient reported outcome”) AND (“breast cancer” OR “breast oncology”)))) AND (LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013) OR LIMIT-TO (PUBYEAR, 2012) AND (LIMIT-TO (DOCTYPE, “ar”) OR LIMIT-TO (DOCTYPE, “re”) OR LIMIT-TO (DOCTYPE, “cr”) AND (LIMIT-TO (PUBSTAGE, “final”)) AND (LIMIT-TO (LANGUAGE, “English”)) AND (EXCLUDE (SRCTYPE, “Undefined”))

These search engines were used : *Pubmed* , *Web-of-Science, Scopus and google scholar*

The first search was performed on January of 2021 globally and the last search on February of 2022 in Europe. There was a restriction on the time period, from 2012 to 2021.

As inclusion criteria, it was defined that the study would focus on scientific articles related to value-based healthcare in breast cancer care with European coverage, between 2012 and 2021.

The type of value-based intervention or approach, implemented in a hospital or department of breast cancer care, to be included in the study was defined as follows: Any step of the VBHC Agenda. Values-based interventions are defined as those that are applied or applicable with the goal of achieving better health outcomes per cost. These approached are based above all on the alignment between the establishment and the healthcare professionals in terms of value for the patient and the sustainability of the healthcare system, first global and after just in Europe.

As an exclusion criterion, it was defined that scientific articles not finished or undefined would be excluded

There were no restrictions on the type of study.

Once the immediate results of the qualitative content analysis had been obtained, an attempt was made to develop a synthesis that would allow the construction or relevant hypotheses, resulting from the conclusions of the primary studies and the final interpretations (165).

There are several definitions for this type of synthesis, but the terms analyse, integrate, synthesise, transform and conceptualize qualitative results are common. Thorne and his co-authors (166) assert that, whatever the different names, these syntheses represent methodological approaches to the development of new knowledge, based on rigorous analyses of existing qualitative research results, with the certainty that these remain intact.

Data analysis techniques

For the analysis of systematic review data, as mentioned, the *Guide for conducting narrative synthesis in systematic reviews,* by Popay and colleagues (167). Narrative synthesis is a form of storytelling, and telling a believable story is central to narrative synthesis, as it can bridge research, policy and practice.

The flowchart that summarizes the synthesis process is shown in figure 8, adapted to the present study from the Guide by Popay and colleagues.

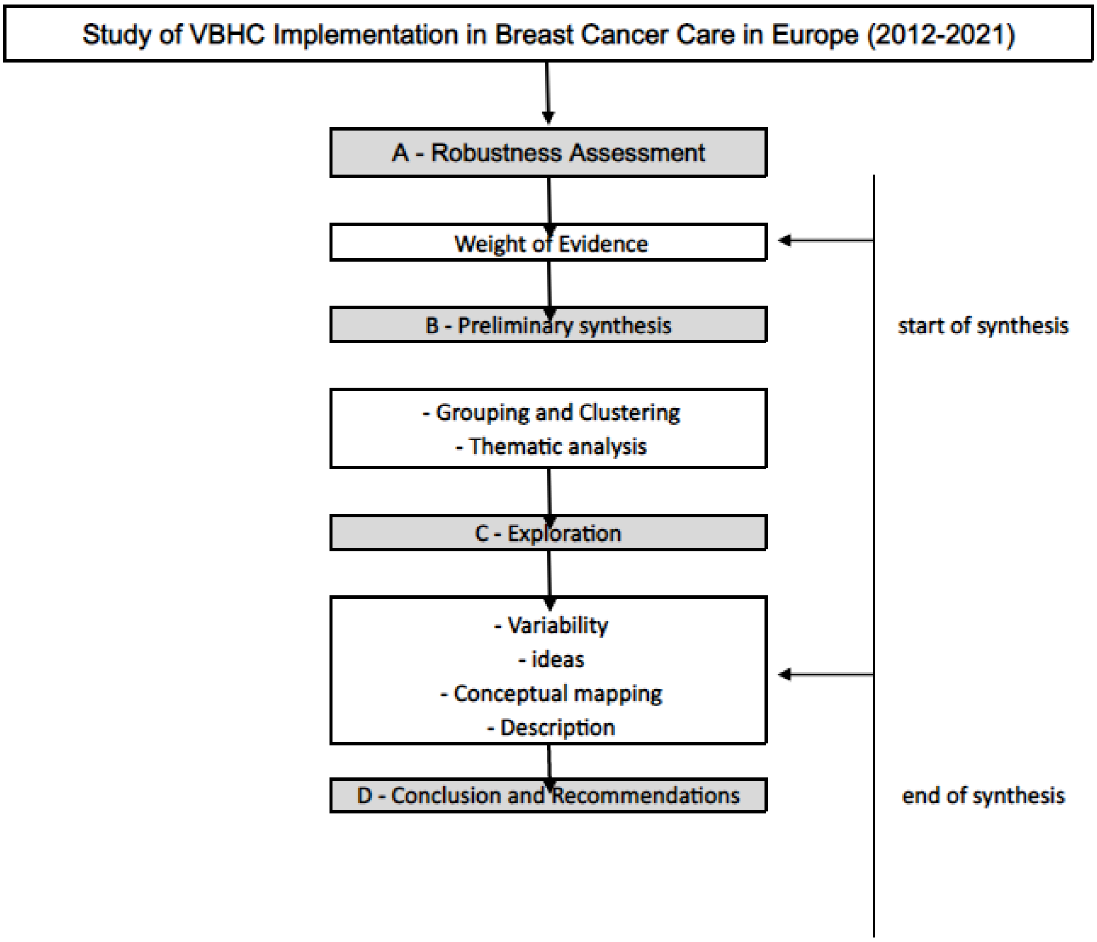

figure 8 : Synthesis process flowchart

The thematic or categorical analysis of the Value Agenda was carried out using NVivo version 11 Plus, research assistance software using qualitative methods and mixed. In the components of the network of ideas, concept mapping and translation, the value agenda was segmented into its six steps, as explained at “I-2.3.4 Value-Based in Breast Cancer Care”.

PART III Results and Discussion

Chapter III-1 Results

1745 records were listed, 12 duplicates were excluded. After excluding time out of 2012-2021, 1615 records remained. After just keeping articles, reviews and conference review, we got 1473 records. By selecting final articles, 1431 records remained. Deciding to keep just English language, we got 1414 records. Physics, astronomy and undefined records were excluded, 1379 remained. Excluding all the records outside Europe,179 articles were fully read and included in the synthesis. (PRISMA – figure 9)

figure 9 : Information Process Flowchart of the systematic Analysis - PRISMA

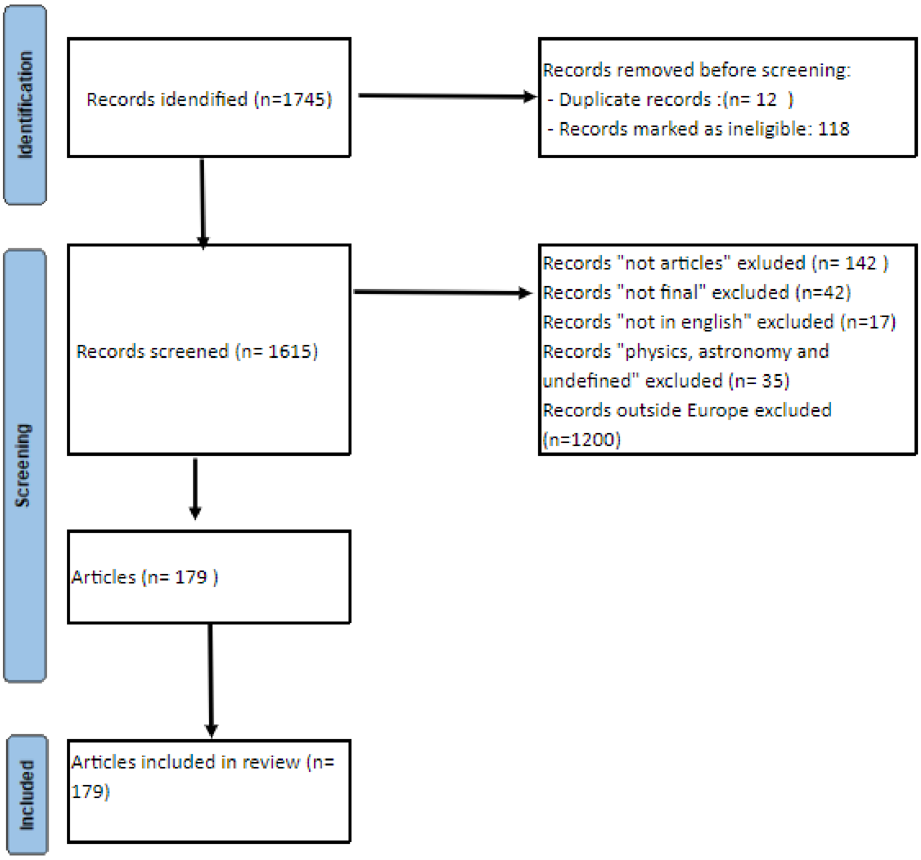

figure 10 : Word cloud of the 179 records

III-1.1 Grouping and clustering

The value agenda described in the 179 records (n=360 codes) included in the qualitative content analysis have been grouped into six steps (Value Agenda), namely, step 1: IPUs (n=35 codes), step 2: Patient-reported Outcomes and costs (n=179 codes), step 3: bundled payments (n=8 codes), step 4: integrated care delivery (n=29 codes), step 5: expend excellence geographically (n=37 codes), step 6: IT platform (n=72 codes).

Thematic analysis

By carrying out the thematic analysis of the value agenda's steps based on the 179 articles and referring to the 360 vbhc codes in breast cancer care in Europe between 2012 and 2021, results were identified in the 6 value agenda's steps.

III-1.1.1 VBHC Agenda step1- IPU and care pathways in Breast Cancer Care

figure 11 : Word cloud of the step 1 of VBHC Agenda : IPU

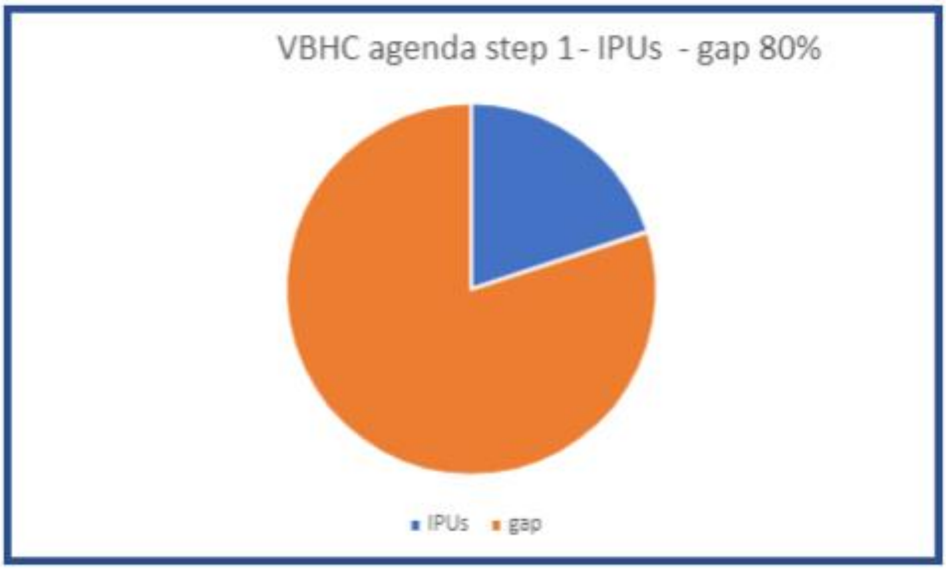

figure 12 : the missing steps "gap" of the step 1 of VBHC Agenda : IPU

III-1.1.2 VBHC Agenda step2 - Quantify outcomes and costs in Breast Cancer Care

figure 13 : Word cloud of the step 2 of VBHC Agenda

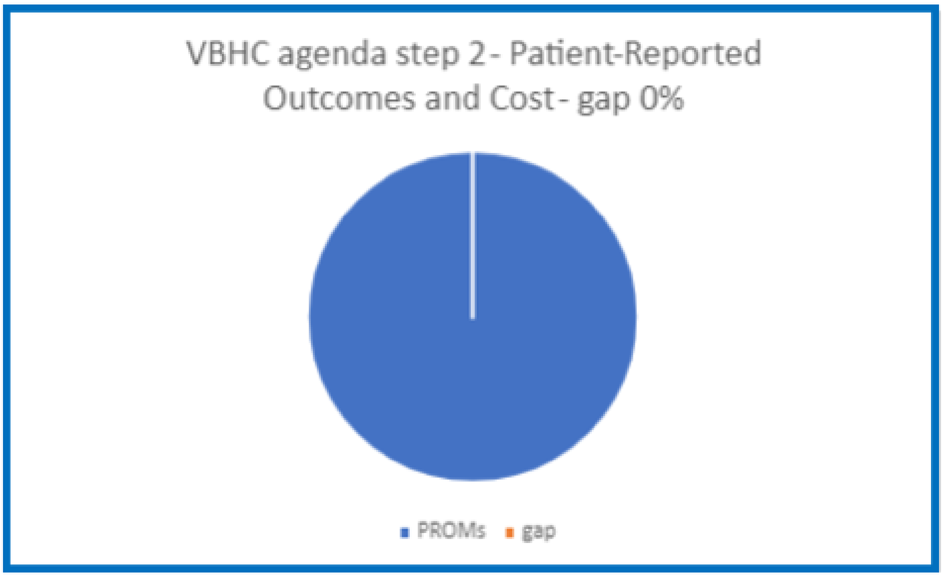

figure 14 : NO missing steps "gap" of the step 2 of VBHC Agenda

III-1.1.3 VBHC Agenda step3: Bundled Payment and Value-based reimbursement in Breast Cancer Care

figure 15 : Word cloud of the step 3 of VBHC Agenda: Bundled Payment

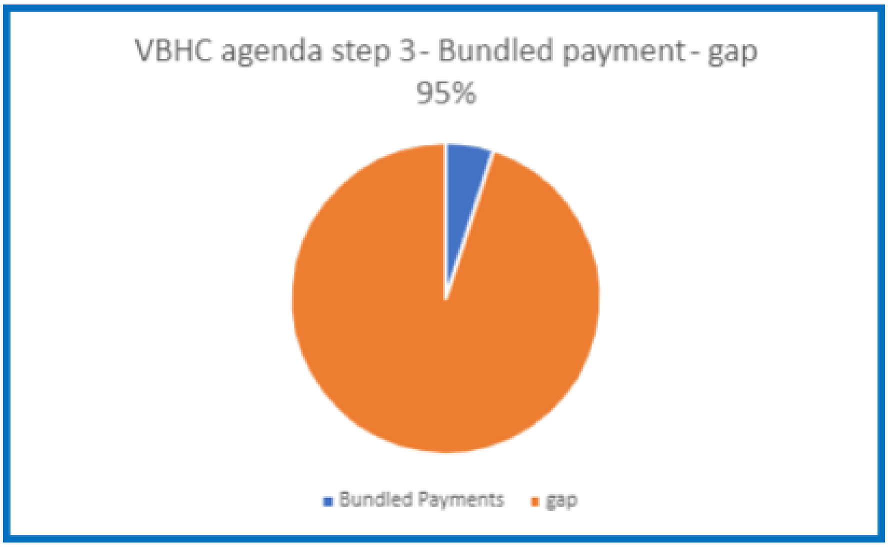

figure 16 : The missing steps "gap" of the step 3 of VBHC Agenda : Bundled Payment

III-1.1.4 VBHC Agenda step4: Integrated systems in Breast Cancer Care

figure 17 : Word cloud of the step 4 of VBHC Agenda: Integrated Delivery

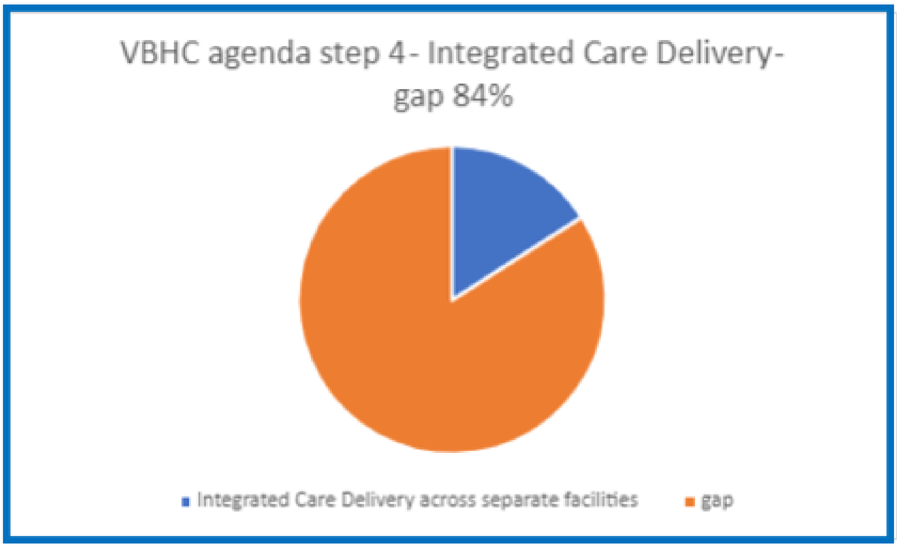

figure 18 : The missing steps "gap" of the step 4 of VBHC Agenda : Integrated Care Delivery

III-1.1.5 VBHC Agenda step5: Geography expansion of care delivery with centers of excellence in Breast Cancer Care

figure 19 : Word cloud of the step 5 of VBHC Agenda:
Geography expansion of care delivery with centers of excellence

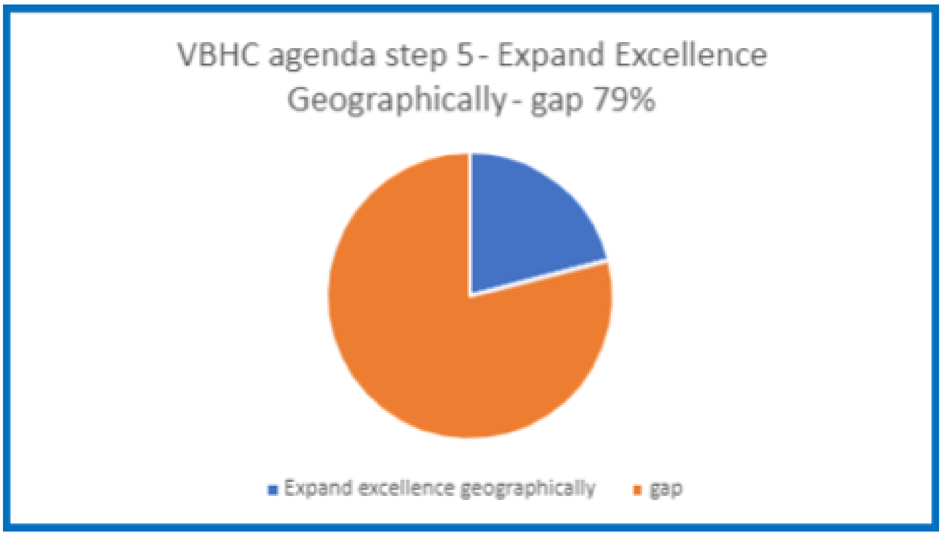

figure 20 : The missing steps "gap" of the step 5 of VBHC Agenda :
Geography expansion of care delivery with centers of excellence

III-1.1.6 VBHC Agenda step6: Information technology (IT) supporting VBHC in Breast Cancer Care

figure 21 : Word cloud of the step 6 of VBHC Agenda: IT supporting VBHC

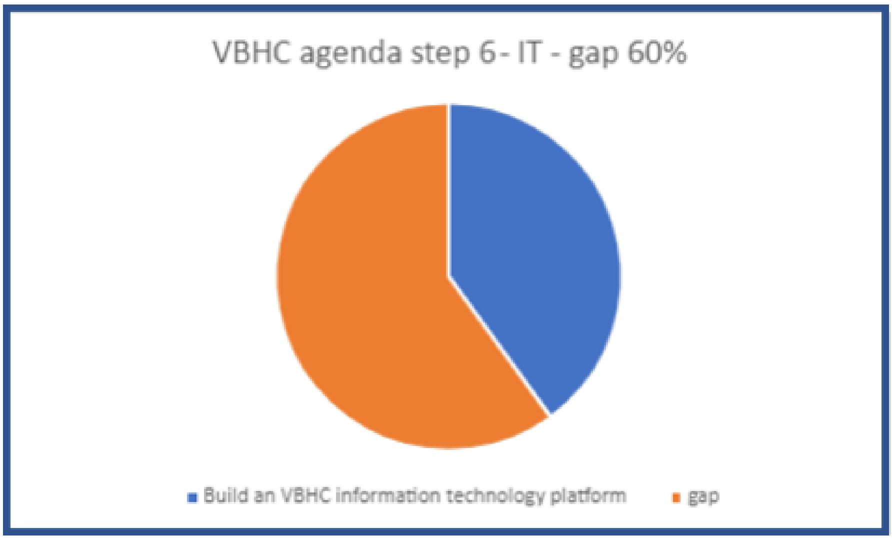

figure 22 : The missing steps "gap" of the step 6 of VBHC Agenda : IT supporting VBHC

III-1.2 synthesis of a qualitative content analysis

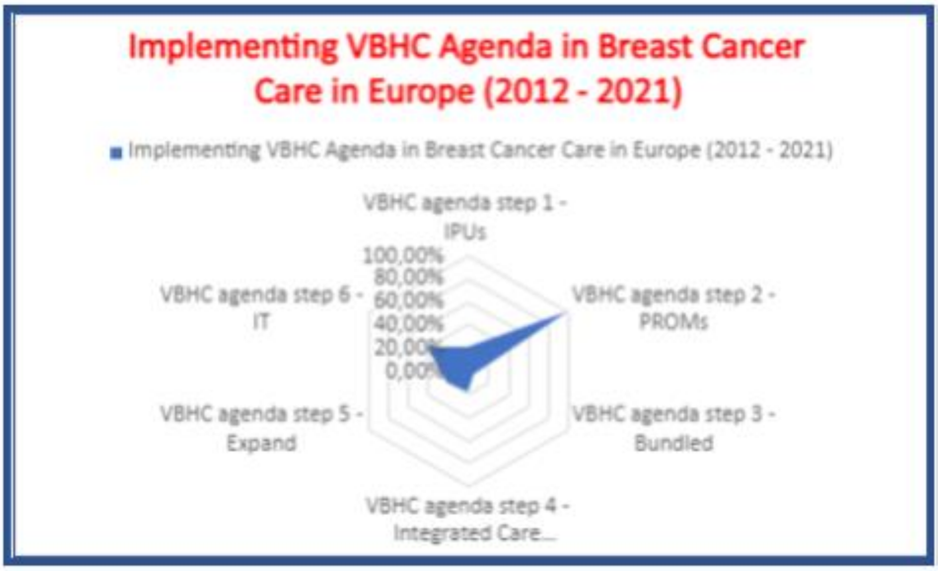

figure 23: Synthesis of the qualitative content analysis of the implementation of VBHC in Breast Cancer Care in Europe (2012-2021)

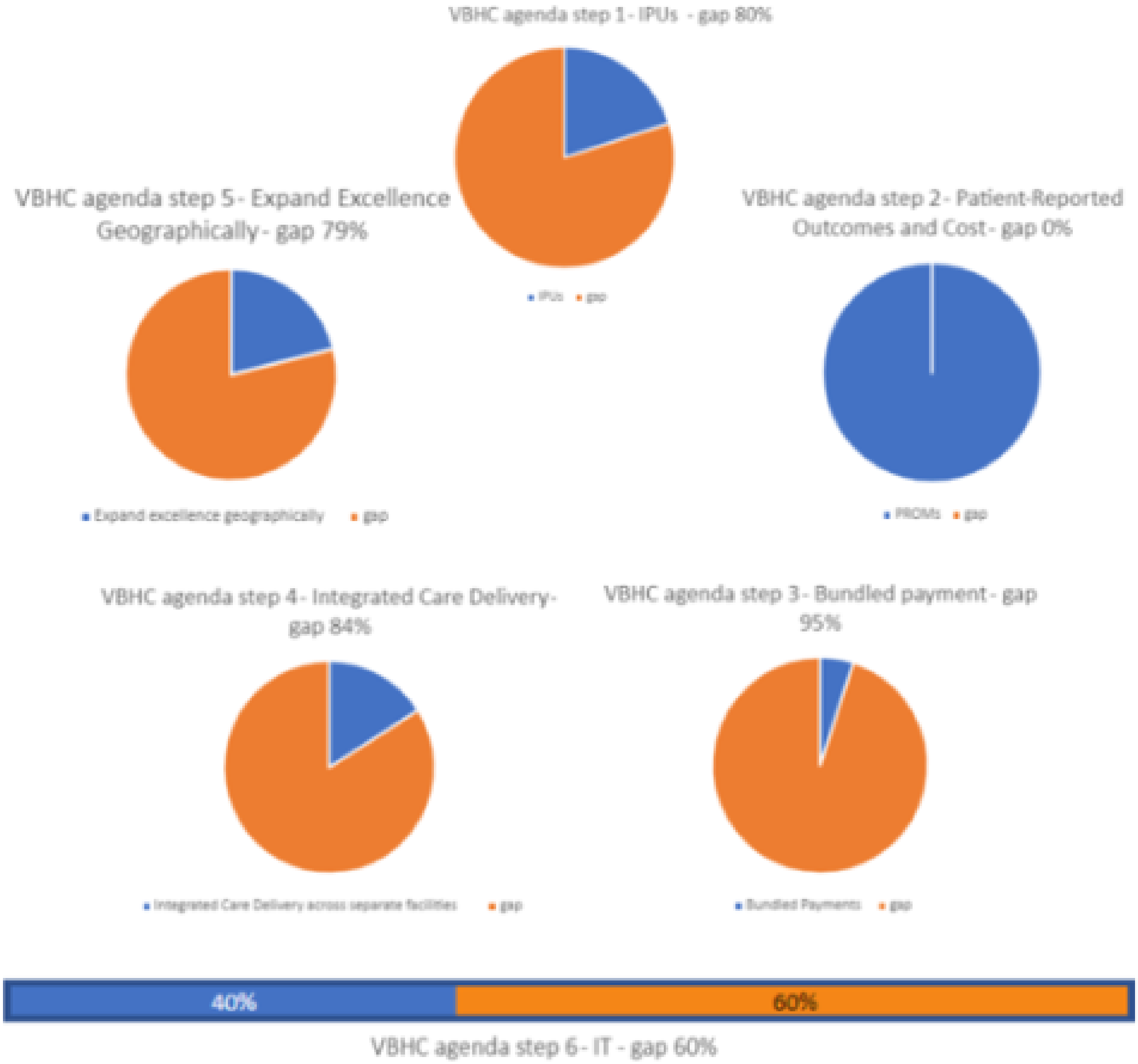

figure 24: VBHC implementation in Breast Cancer Care in Europe (2012-2021)

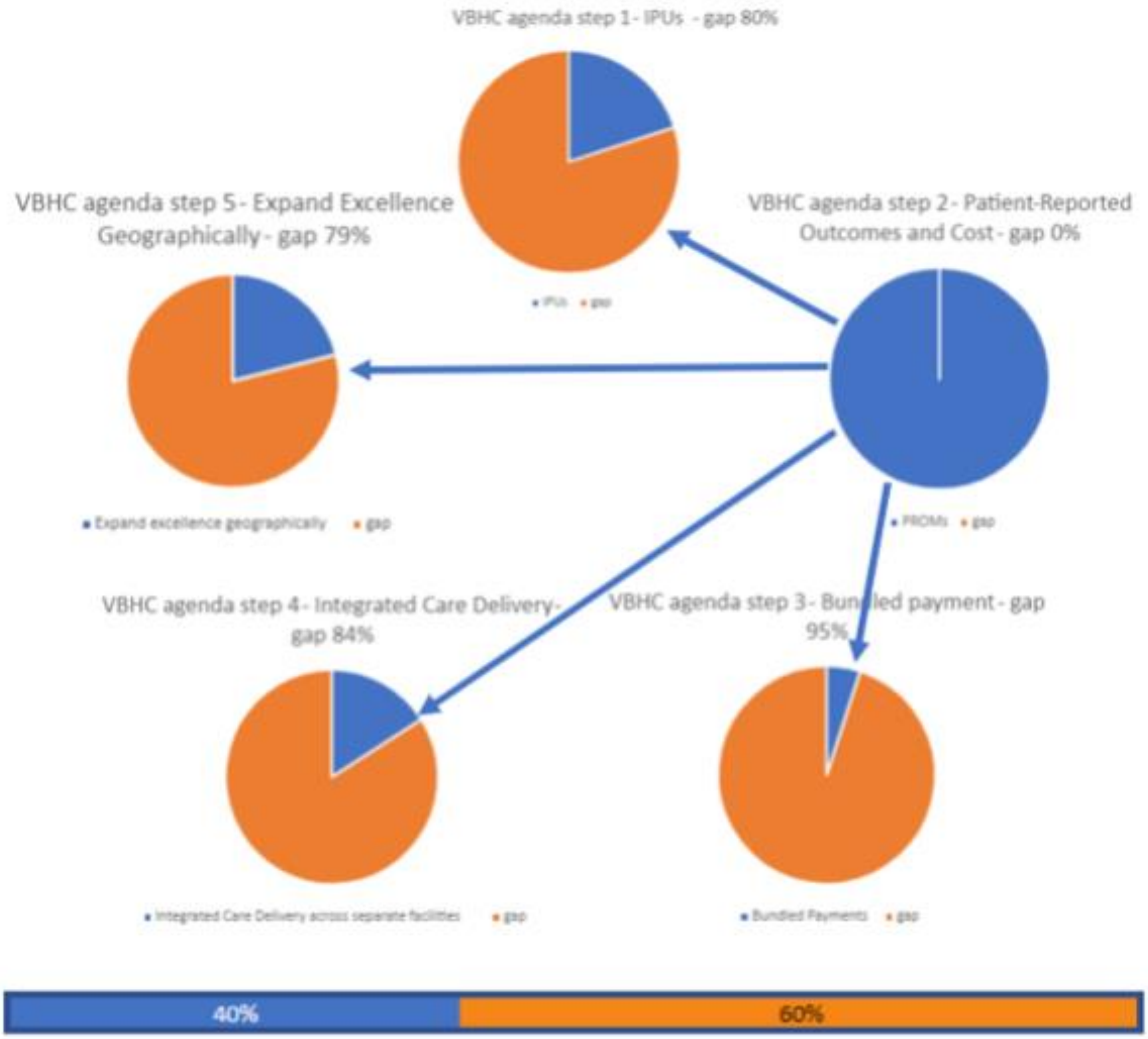

figure 25: PROMs and costs step 2 of the VBHC Agenda: the spearhead of the implemantation of VBHC in Breast Cancer Care in Europe (2012-2021)

The qualitative Content Analysis of the VBHC implementation in Breast Cancer Care in Europe demonstrates that the 6 steps of the VBHC agenda have not been applied yet. All stakeholders are well aware of the importance of a patient-centred health system. PROMs (figure 25) are the spearhead of VBHC implementation in Brest Cancer Care in Europe (2012-2021).

Chapter III-2 Discussion

As explained in the introduction, overuse and underuse of health care interventions are expandingly understood as main subscribers to the loss of public resources. Overuse is described as the delivery of medical services that are more probable to bring harm than good (135). The injury can be physical, psychological, financial or societal (inequity). Overdiagnosis is seen as the driving force behind “too much medication”, the topic of considerable campaigns by the BMJ, the Dartmouth Institute and numerous other organizations against the damaging and financial repercussions of over testing and overtreatment (136). Overdiagnosis unnecessarily turns people into patients. Underuse is interpreted as the inability to use effective and cost-effective medical interventions that can prevent morbidity and mortality (137). There is a real urgency to reassign resources from low value care to high value care and to prioritize what matters to patients with their choices and needs.

III-2.1 VBHC Agenda step1- IPU in Breast Cancer Care

The histogram (figure 26) highlights the Netherlands and Denmark as the leaders of implementing IUPs in Breast Cancer Care in Europe between 2012 and 2021.

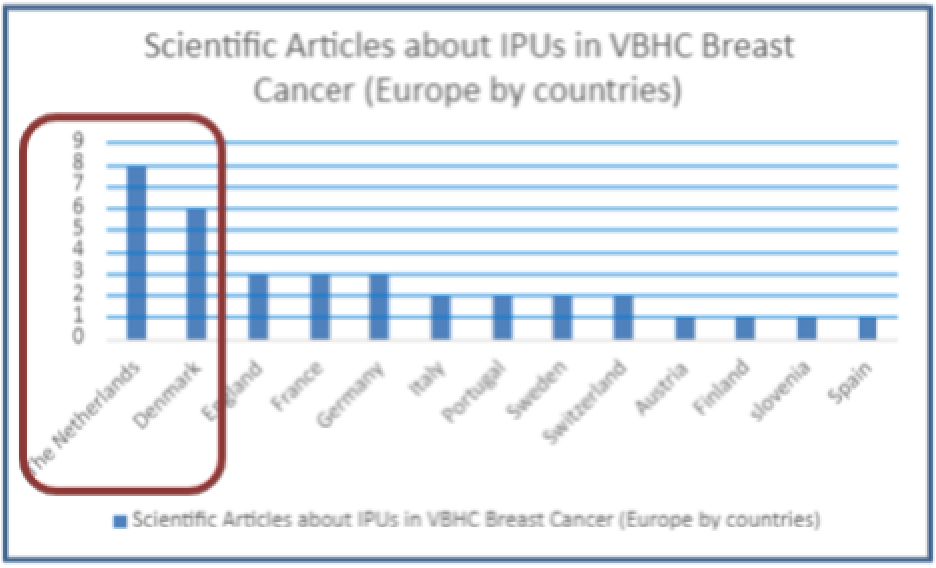

figure 26: histogram of step 1 IPU of VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - The Netherlands

Even if the implementation of value-based healthcare is moving slowly, government and healthcare stakeholders are really interested in VBHC. The Netherlands has a universal system established on private insurers and healthcare providers, with a legal mandate to buy insurance. The government controls the insurance across the reimbursement process with regulations. A payroll tax provides for half of costs that are not paid by insurance premiums. Insurers have a leader role in the system, as the principal guardians of cost control strategies. That is why the system is decentralised. Thus, the Dutch main policy in healthcare relies on cost control. Even if Parliament has pushed the government for moving towards outcome-based payments, this interest has not turned into a coordinated national policy with the application of VBHC core concepts. However, insurers and healthcare providers have demonstrated considerable interest. The decentralized system enables opportunities for locally innovation, with various important experiments ongoing. And some of them are initiated by health insurers. It has nevertheless conducted to a deficiency of central decision-making, one of the main obstacles to the widespread adoption of VBHC principles.

The Dutch VBHC success of SANTEON

Santeon is a Dutch network of seven hospitals. They started VBHC in 2015 (168). One year and a half later, they had already performed outstanding outcomes, by reducing in approximately 30% unnecessary inpatient stays and in 74% the percentage of resurgeries consequences of breast cancer surgery lack. They succeeded in doing so just by switching the centre of the strategy from matching protocols and guidelines, to focussing on what matters to patients (168). They started creating IPU with 5 medical conditions, as breast cancer, prostate cancer, cerebrovascular accident and hip arthrosis. They implemented a scorecard of outcomes, costs and process indicators for each medical condition. Afterwards, Santeon Physician began to mutually distribute their outcomes with the 7 hospitals to promote internal learning during standardized improvement cycles for each medical condition. This included data collection, data analysis, cataloguing areas of improvement and achievement of improvement action steps. At last, following 3 improvement cycles, Santeon showed its acknowledge results outside. Santeon and payers committed to settle bundled prices and bonus.

Transparency was pulled over health outcomes. The Santeon experience demonstrates that all stakeholders must commit to succeed in supplying value in health care.

2nd - Denmark

Denmark has a culture of a public and integrated health system. Most health care funding comes from state, regional and local incomes. If most hospitals are publicly managed, some private and public-private collaboration exist. In 2016, a framework was published under the Danish Regions to defend the implementation of VBHC in Denmark. The Danish VBHC translation describes a rewording of the Porter's VBHC concepts to take into account some of the probable complications of turning general concepts into practice.

Finsenscentret turned to be a regional value-based pilot project in 2018. This project deals with some value-based management initiatives for various patient groups, such as "Nursing consultations" for breast cancer surgery patients.

III-2.2 VBHC Agenda step2 - outcomes and costs in Breast Cancer Care

The Netherlands, the United Kingdom, Sweden have already taken up the subject of quality indicators. Some countries have been working on this for more than twenty years and collect PROMs and CROMs, respectively from patients (through the sending of quality of life questionnaires) and from clinicians (through the keeping of data for defined pathologies). The results are published comprehensively, transparently and accessible to everyone.

Breast cancer treatments differ extensively from institution to institution and country to country. Today, because varied treatments can bring similar survival outcomes, the value each patient puts on the potential gains and losses related with each treatment option performs a crucial role in a treatment preference.

It has been demonstrated that monitoring of symptoms and health-related quality of life (HRQoL) ameliorate not only patient satisfaction, but also clinical outcomes, by reducing emergency department visits and hospitalizations, longer duration of palliative chemotherapy and by improving quality-adjusted survival (139). Patient-reported outcomes measures (PROMs) are being applied more often to control HRQoL, because both providers (health professionals) and patients' family and friends pay less accurate attention to HRQoL outcomes. They are collected by requesting patients to fill in a survey about their functioning and well-being. PROMs tools such as the C-30 (for cancer) and BR-23 (particularly for breast cancer) quality of life questionnaire from the European Organization for Research and Treatment of Cancer (EORTC) have been validated for research and routine use. They are widely used in a clinical research setting, and start being implemented more and more into routine clinical practice with e-PROMs.

The International Consortium for Health Outcomes Measurement (ICHOM) is working to elaborate standardized health outcome measures for the most common diseases. Their mission is to "unlock the potential of value-based health care by defining global Standard Sets outcome measures that really matter to patients for the most relevant medical conditions and by driving adoption and reporting of these measures worldwide" (48). These standard sets have a fourfold objective: 1) Cut down healthcare costs by anticipating medical errors and needless treatments; 2) Defend informed decision-making and enable patients to select their doctor based on valid data; 3) Defend informed decision-making by allowing physicians to better debate treatment options with their patients; 4) Enhance the quality of health care by allowing physicians to compare their health outcome data with those of other providers.

The breast cancer set of standards (figure 7) was put out in JAMA Oncology resulting in a rigorous process in which patients, healthcare providers and health registries gave priority to a range of potential health outcomes concerning the relevance of those outcomes to patients (140). Therefore, these specified outcomes are picked up in all patients: general well-being, physical, emotional, cognitive, social and sexual functioning, work capacity, anxiety, depression, insomnia, financial impact, pain, fatigue and body image. Furthermore, patients undergoing surgery and/or radiotherapy are invited to fill out questionnaires about satisfaction with breast(s), arm symptoms, while patients undergoing systemic treatment are questioned about vasomotor symptoms, peripheral neuropathy, vaginal symptoms and arthralgia. Carrying out the set of standards is both complicated and time-consuming. This needs a committed team and an adequate partnership with the hospital's IT team.

It is crucial to have a ready database. The patient's personal treatment plan must be examined, as patients undergoing distinctive treatment procedures will fill out various questionnaires. These PROMs must also be collected in a timely manner. The paper-and-pencil technique may be easier to realize at first. Besides it needs more people to encrypt questionnaires responses into a database. However, the electronic filling of the questionnaires, due to emails sent at regular intervals to the patients, does not need supplementary processing of the data by the employees of the site.

figure 7 : The ICHOM Breast Cancer Standard Set comprises items related to degree of health, survival, disease control, and disutility of care ichom.org

The histogram (figure 27) shows the Netherlands, UK-England, Germany, Denmark and Sweden as the leaders of implementing Patient-reported outcomes in Breast Cancer Care in Europe between 2012 and 2021.

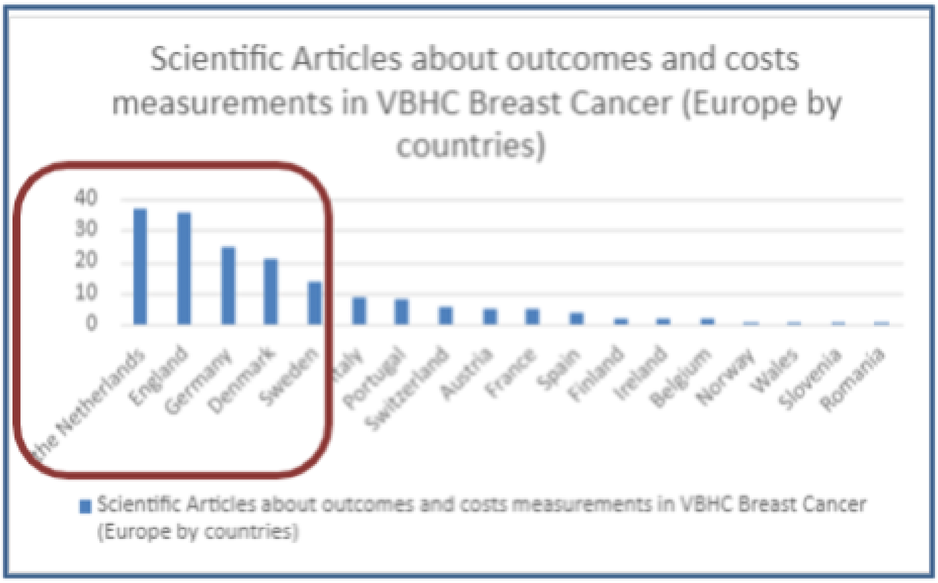

figure 27: histogram of step 2 Outcomes and Costs of VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - The Netherlands

The Dutch health system is based on several concepts such as universal access to care, compulsory health insurance accessible to all and good quality of care.

In the Netherlands, quality indicators are collected from hospitals by the Dutch Institute for Clinical Audit (DICA), the Dutch Institute for Clinical Audit. The indicators' data is published exhaustively and in open data on a dedicated website, in the form of an excel file. The quality indicators measured by DICA are very complete, there are CROMs, PROMs, PREMs, process and structure indicators.

The DICA Institute (Dutch Institute for Clinical Audit), a non-profit organization funded by the state and by private initiatives, was established in 2011 with the aim of developing and coordinating other national results registers covering several pathologies, such as Breast Cancer (141).

2nd - UK - England

The Care Quality Commission (CQC) (142) is in charge of collecting PREMs. The CQC conducts surveys on the experience of patients and the quality of their care in different care services. The aim is to study patient satisfaction with the health services they use by asking them questions, as listening, respect, explanations of treatment to patients by medical teams, waiting time in care services, etc. PREM data is published online in the form of an annual report on the CQC website.

The NHS Digital (143) is in charge of collecting PROMs from hospitals. PROMs are collected by hospitals. Patients are asked about their difficulty in moving around, pain assessment, ability to perform their usual activities, the possibility of returning to work, etc. In 2009, the National Health Service (NHS) also made it compulsory for hospitals funded by the NHS to collect PROMs. This collection would be later extended to other pathologies such as mental health, cancer and chronic diseases.

The My NHS site makes it possible to compare the performance of healthcare establishments at national and regional level, in particular based on quality life and clinical outcome indicators that are important to patients, such as PROMs, CROMs, PREMs, the characteristics of the patient (sex, age, chronic pathology, etc.), lengths of stay and activity volumes (for example, the total number of surgeries performed for a given hospital)

The NHS Choice site, the official public website of the NHS in the United Kingdom, provides a comprehensive health information service (hospitals, general practitioners, specialists, etc.) and disseminates quality indicators for healthcare establishments or physicians. The goal of this tool is to help people make acquainted choices with care by publishing comparable data on healthcare providers and taking into account the geolocation of the patient. Patients also have the possibility to rate and comment on the care services they have used, and which are published on the site. The results can be classified according to organizational data (possibility of making an appointment on the internet), the experience on the overall quality of care received, the rate of patients with chronic diseases (asthma, diabetes, hypertension, etc.) followed by a physician, the quality of the care service or consultation (duration of consultation, listening, etc.), patient’s age, the CQC inspection note available for hospitals. The NHS Choice is the first website allowing users to compare health data with each other, including quality indicators, with 48 million unique visits per month, responding to a real patient need. Data from other existing databases or institutions such as the CQC are also available. The responsibility and collection of quality indicators is attributed to the National Health Service, that is to say to the English payer and not to the National Institute for Health and Care Excellence which is the equivalent of the HAS. In France, the collection and publication of quality indicators is entrusted by the HAS.

3rd - Germany

Germany, a global healthcare leader, is also an initial adapter of many principles of value-based healthcare. Martini-Klinik evolved into the first hospital to demonstrate that better data collection aimed at patient experience can make better overall outcomes.

4th - Denmark

In Denmark, the Ministry of Health funds 68 quality registries with open benchmarks without any duty to communicate outcome data. Each provider declaring at least 90% of patient cases is qualified for financial allowance to reward collection efforts (144)

5th - Sweden

Sweden is a leader in VBHC adoption, with evidence-based guidelines, disease registries and the first steps towards outcome-dependent reimbursement. Universal healthcare is mainly funded by taxpayer. It focuses on guaranteeing equal access to quality of care for all legal residents, asylum seekers and undocumented people. Sweden has not applied a large-scale version of value-based healthcare (VBHC), but the system is built to use decades of evidence-based treatment guidelines and disease registries. Furthermore, the Swedish health system is moving towards outcomes-based reimbursement for specialist care. The National Board of Health and Welfare (Socialstyrelsen) guarantees quality standards by overseeing health care, diffusing information and building up norms and standards for medical care, including collecting and analysing data. To offer transparency, performance data by providers are publicly available. This permits patients to figure out informed decisions about their treatment.

Due to two main reasons, there is not accurate plan at the national level to move away from a fee-for-service model. Firstly, the system is decentralized. County councils and municipalities manage their costs and payments. Then, payment mechanisms already include capitation (in which a fixed amount of money per patient per unit of time is paid previously to the provider for delivering health services), fee-for-service and performance-based elements. The government moved forward patient-centred care laws on patient safety.

Central funding is received by about 100 disease registries, with approximately 60% of them covering more than 80% of their focus population. Registries include standardized and individualized data regarding patient issues, medical interventions and port-treatment outcomes. They are controlled yearly by an executive committee, financed by the central government and by the county councils. They are administered by specialized organizations. Registries are connected. Furthermore, the implementation of electronic health records focusses on providing better integration of patient outcomes.

Until now in Sweden, there are some components that strengthen patient outcomes and value that are essential to comprehend and go beyond costs. Introduction to high-quality data is a fundamental element in assessing the value of healthcare. And Sweden's quality health registries and digital health records offer important chances to collect and share real-world evidence (RWE) on health outcomes.

The Swedish quality indicator collection system is very comprehensive and transparent. There are more than 100 specific national quality registers, the National Quality Registries (NQR), each being specific to a given pathology and responsible for collecting quality indicators including PROMs and CROMs. The collection of PROMs by the NQRs is mandatory for hospitals to obtain a high level certification (145). All the data is then published in the form of an annual report specific to each NQR, easily accessible on the internet. The results presented are very detailed and updated every year.

In Sweden, the development of quality indicators was initiated in the 1970s and responds to the founding principle of the Swedish Healthcare Act (1982) according to which "the Swedish healthcare system must ensure access to quality healthcare for the entire population. Care should be provided equally with respect for the dignity and integrity of all individuals (146). **T**he system must focus on the patient while being efficient, egalitarian and accessible to all within a reasonable time.

To do this, National Quality Registries (NQR) were developed in the 1990s to collect data on quality and results. They were created and supported by the medical profession (physicians, nurses, physiotherapists in particular) and are now 70% funded by the State, through the Ministry of Health and Welfare, and 30% by the counties and regions. This funding ranges from €50,000 to €800,000 per year per registry.

Each registry is managed by a multi-professional set of experts and sometimes patients. They respond to different objectives and pathologies. They are also used to develop statistics to support clinical research. They contain information, such as outcomes that matter to patients (including PROMs and CROMs), care processes (including PREMs and patient experience feedback), patient demographics, organization and structure care, the types of institutions (university, regional, rural and private). In the Swedish healthcare system, NQR registries are required to incorporate PROMs to obtain certifications.

A review of the latest annual funding requests shows that (147) currently 96 out of 108 quality national registries include PROMs or PREMs. Registries include both generic and disease/symptom-specific measures, and about 40% of registries include PREMs (148). Only 10% of hospitals report not collecting ant PROMs or PREMs.

All the results collected by the NQR registers are published in the form of an annual report specific to each pathology and easily accessible to patients. These reports are available on the sites of each NQR. The results are very detailed. The average results of the establishment’s quality of life (PROMs) or patient satisfaction (PREMs) questionnaires, is compared to the expected target value and the national average. Sweden has also developed a national collaborative program to foster the development of VBHC models.

III-2.3 VBHC Agenda step3: Bundled payment and Value-based reimbursement in Breast Cancer Care

In the past, health systems were based on the division of labour. Responsibility for cost management for the health care system rested with payers (health insurance, health authorities) and providers (facilities delivering care) were accountable for the quality of care provided to patients. Nevertheless, a fundamental principle of VBHC is that payers and providers split responsibility and cooperatively manage cost and quality. The progress of transition from fee-for-service to value-based payments for health care is practically sure to quicken in the following years. Therefore, caregivers will need to master how to prosper in the new environment.

A redistribution of resources, as the release of resources and therefore reinvestment, from low value care to high value care is seen by the EXPH as the absolute prerequisite for sustainable and resilient European healthcare systems.

The search for more cost-effective payment systems

Most European efforts to evaluate the value of healthcare over the past decade have aimed on what Porter and Teisberg characterize as processes rather than outcomes. The shift from lump sum payments to “per episode” payments to one or more providers produces progress to a more organized approach to treatment by compensating a single care pathway and making better use of high-priced services, such as hospitals (149). Proponents of these payment systems claim that they are particularly efficient for the treatment of chronic diseases. The Netherlands initiated such a system in 2010 for the management of diabetes, chronic obstructive pulmonary disease (COPD) and vascular risk management. German insurers have been negotiating integrated contracts with various healthcare providers since 2000.

Bundled payments turn providers more financially responsible than with the fee-for-service system for the whole cost of a patient’s treatment and recovery.

The histogram (figure 28) shows Germany and UK-England as the leaders of implementing Bundled payments and value-based reimbursement in Breast Cancer Care in Europe between 2012 and 2021.

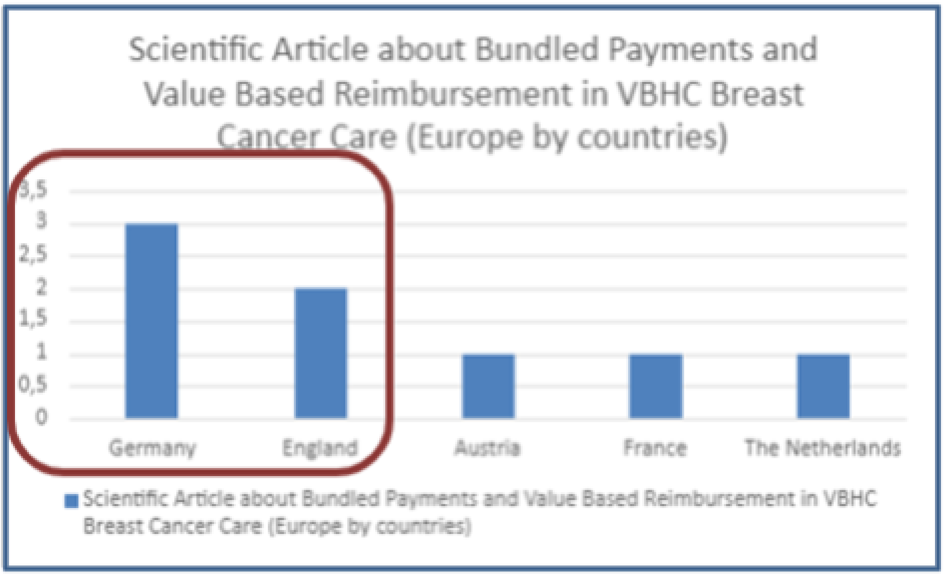

figure 28: histogram of step 3 Bundled payment of VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - Germany

Paying for performance and according to more power to the regions in taking charge of health policy are other strategies carried out to meliorate the health system. Over the past few decades, data collection has grown in prominence. Germany ensures healthcare for everyone. The coverage is universal for all legal residents. Most residents are covered by the Statutory Health Insurance (SHI) system (Gesetzliche Krankenversicherung, or GKV). This is composed by 134 health funds supported by employee and employer payroll taxes (Bismarck health financing system). Only 11% of Germans pay a private health insurance.

The value-based healthcare (VBHC) agenda is managed by the Institute for Quality and Efficiency in Healthcare (IQWIG). Moving to a full VBHC system will take some time, but efforts are being made to expedite the transition. The German Diagnosis-Related Group (DRG) system uses fixed-price fees and is not governed by fee-for-service. Some clinics and providers keep on moving to a VBHC delivery system. Current reforms are not a sweeping plan to fully adopt value-based care, though they do call for a more compliant, digitized, and patient-centric healthcare system.

2nd - UK-England

In comparison to other countries, the United Kingdom has the most public system with a tax-based system (Beveridge health system funding) that supplies universal coverage to all citizens through the National Health Services (NHS). NHS England has important authority over how government funds are used. Clinical Commissioning Groups (CCGs) were set up to supervise primary and specialist care at the local level (150). Private clinics or hospitals propose selective services concomitant with the NHS system. These private providers are remunerated out of pocket or through private supplementary insurance. More than 10% of the population pay a private insurance (151).

The UK is progressing towards a patient-centric system that delivers maximum value, thanks to innovative payment models and team-based ways. NHS England monitors and supervises all publicly funded healthcare. NHS delegates the delivery of acute care to local trusts and hospital groups.

The NHS has been experimenting with new payment models, such as bundled payments by implementing the Quality and Outcomes Framework. These accomplishments complete the duty of the National Institute of Health and Care Excellence (NICE), which produces and certifies evidence-based guidelines.

During the last decade, NHS England has investigated and applied policies to move from a healthcare system that is at present managed around medical specialities and fee-for-service towards a patient-centred system which affords maximum value. Although some fresh reforms have been applied to reduce costs in reaction to national austerity and rising health care costs, there is general support among policymakers and other health stakeholders for implementing more patient-centric care that augments value.

NHS England has not yet generally implemented **bundled payments**, but operates with a payment system, named Best Practice Tariffs (BPT). It recompenses providers who deliver high quality of care through predetermined patient pathways (152). The aim of BPT is to decrease clinical variation by encouraging the choice of best practices. The NHS designated a series of standard for diverse conditions that can lead to enhancements in care processes from admission to discharge. When providers cooperate in the BPT scheme, they earn a slightly lower base fee for procedure. And, if they match all the standards, they are rewarded with additional funding which actually compensates for the depreciation in the base fee. Fines are also provided for in the event of non-compliance with quality-of-care indicators.

III-2.4 VBHC Agenda step4: Integrated care delivery in Breast Cancer Care

The histogram (figure 29) shows UK-(England & Wales) and Germany as the leaders of implementing integrated care delivery in Breast Cancer Care in Europe between 2012 and 2021.

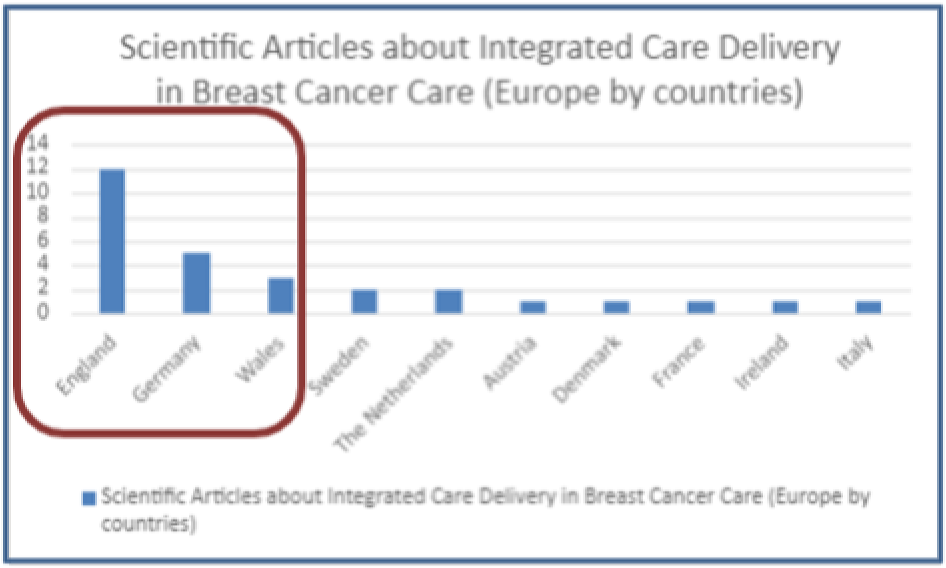

figure 29: histogram of step 4 Integrated care delivery of VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - UK-England + 3rd UK-Wales

In recent years, UK best results have been reached when organizations have worked together. Integrated care systems (ICSs) are cooperations of organizations that collaborate to plan and delivers joint health and care services. The goal is to meliorate people lives.

The aim of integrated care systems (ICS) is to bring partners organizations. By doing so, outcomes wil be improved in population healthcare. ICS will also help NHS support broader social and economic development

2nd - Germany

Germany aimed at meliorating the process of delivering care, rather than measuring patients' outcomes and experiences. Growing minimum volumes of procedures and building centralized care units (IPUs- Integrated Practice Units) practising exclusively in particular diseases or procedures are the most frequent try-outs to ameliorate quality in Germany.

III-2.5 VBHC Agenda step5: Geography expansion of care delivery with centers of excellence in Breast Cancer Care

The histogram (figure 30) shows The Netherlands, UK-England and Germany as the leaders of implementing Geography expansion of care delivery with centers of excellence in Breast Cancer Care in Europe between 2012 and 2021.

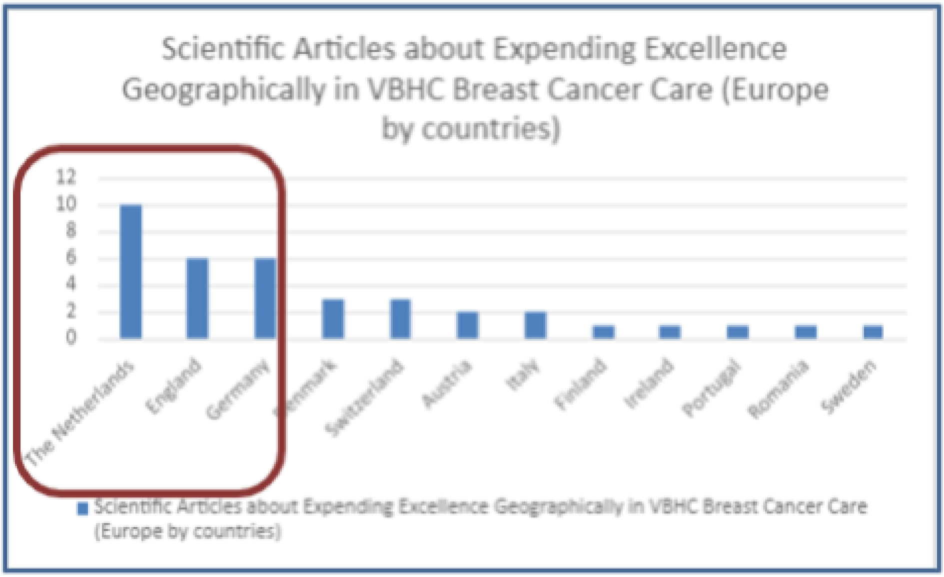

figure 30: histogram of step 5 Geography expansion of care delivery with centers of excellence of VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - The Netherlands

The Dutch healthcare has eight independent academic hospitals set across the Netherlands. They have been operating as tertiary referral centres for managing the most complex patients. They are comparable to centres of excellence in Norway and England.

Some national cancer centres of excellence are famous, such as the Antoni va Leeuwenhoek Hospital. This hospital has been supplying high-quality cancer care to patients across the Netherlands.

2nd – UK-England

In the UK there is a wide variety of data sources for collecting quality indicators, both clinical outcomes (CROMs) and patient-reported outcomes in terms of quality of life (PROMs). The collection of PROMs by the National Health Service (NHS) is also mandatory for four target pathologies: knee surgery, hip surgery, varicose vein surgery and hernia. The UK model is very transparent. 100% of collected results are published in the form of online reports or accessible through public NHS databases (My NHS and NHS Choice) which allow patients to choose their hospitals and healthcare professionals based on numerous quality indicators. These are easy to access and intuitive for patients. The NHS Choice database is very popular with patients and accounts for 48 million visits per month, thus meeting a real demand. The responsibility and collection of quality indicators is entrusted to the NHS. The UK was among the first countries to collect patient feedback on their healthcare system. Since the 1990s, quality indicators have been collected by three different structures: the Care Quality Commission, the NHS Digital and the National Joint Registry.

3rd - Germany

Germany already performs as the number 1 worldwide with Martini Klinik prostate Center, by performing more than 2600 prostate cancer surgeries per year. The specialisation in a single disease allows Martini Klinik to deliver a very high diadnostic and treatment standard.

As Gernany already succeeded with Martini Klinik and prostate cancer, they can design the same VBHC model for breast cancer.

III-2.6 VBHC Agenda step6: Information technology (IT) supporting VBHC in Breast Cancer Care

The histogram (figure 30) shows The Netherlands, UK-England, Denmark and Germany as the leaders of implementing IT supporting VBHC in Breast Cancer Care in Europe between 2012 and 2021.

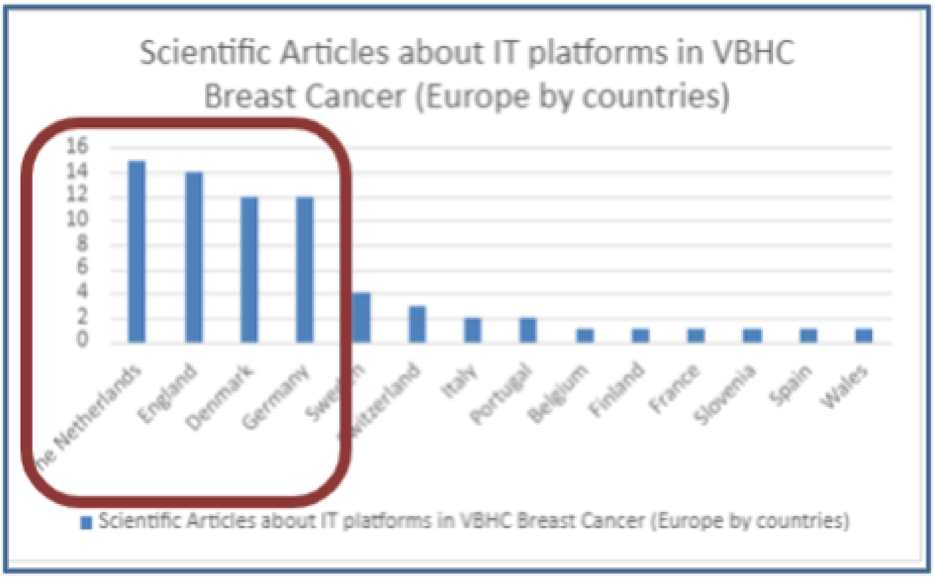

figure 31: histogram of step 6 IT supporting VBHC Agenda in Breast Cancer Care in Europe (2012-2021)

1st - The Netherlands

Both disease registries and electronic health records have been used in the Netherlands. A new national electronic health records system is about to be provided. The restricted volume of data sharing between health professionals is just regionally achievable at the moment. Electronic health records are extensively employed by healthcare providers. Nonetheless, this IT efforts need some fresh injection of government support to enable national data sharing.

In the Netherlands, individual providers and the government are exploring to meliorate the interoperability and data sharing between local providers and patients (154). The government has determined a national IT strategy for VBHC (155).

2nd - UK-England

The UK health information technology system moves slowly. Policymakers have favoured improving the reach and interoperability of health information technology. In 2009, NHS England implemented Patient Reported Outcomes Measures to assess the quality of care supplied from the patient point of view. Much of the advancement in data collection has been realized in the acute care framework.

England has carried out more “values-based” modifications in its healthcare system than other European countries. The National Health Service (NHS) is divergent from its “European neighbours”. More centralized, the NHS is financed by general taxation, containing national insurance contributions, and is both publicly funded and administered mainly through the public sector, even though market reforms have firmly inserted private providers into England during the last decades (157). Although no single health system has already achieved all steps of the value agenda, England has supported the concept of value as outcomes by cost. England has also implemented IPUs and integration of primary and secondary care throughout the patient care pathway to provide value (158).

3rd - Denmark

Danish society is commonly highly digitized. This also applies to the healthcare sector. The development of e-Health in Denmark is based on public-private cooperation between government, regions, municipalities and industry. This has taken innovation and implementation to a level where almost all basic information from different health sectors has been digitized and made shareable. Furthermore, one of the key elements of e-health in Denmark is the Danish civil registration system which enables a unique digital identification of each citizen.

4th - Germany

Germany has registries for main diseases, such as cancers, tumours. They are usually regionally organized and unlinked. Generally, German medical associations manage the registries. That is why stakeholders, like insurance companies and healthcare providers, cannot get any data from them due to rigorous data protection laws. The Institut für das Entgeltsystem im Krankenhaus (INEK), supervises the hospital remuneration system in Germany. INEK also collects data on inpatients’ costs. Any reporting is free-willed and only deals with inpatient treatment.

With a new legislation, digitization is progressing in German healthcare with DiGa applying the new German reimbursement pathway. But, digitization has not yet proceeded in an exchange of digital data between hospitals and outpatients physicians.

PART IV CONCLUSION and RECOMMENDATIONS

IV-1 Conclusion

In the study, countries that have high levels of spending on healthcare also tend to have a presence of outcome-based payment approaches. Higher healthcare spending tends to correlate with many of the elements needed to support VBHC approaches. Of those countries spending more than 10% of GDP on healthcare, the Netherlands, England, Sweden, Germany, France all are developing or using interoperable electronic health records (though full interoperability remains a goal). All these countries also have stakeholder support for VBHC. Moreover, in countries where spending on healthcare is high, there is a powerful incentive to find ways to cut costs by implementing VBHC in Breast Cancer Care.

Growing consideration is being paid to reporting patient outcomes in a standardized manner in Breast Cancer Care. By committing physician leaders, outcome researchers and patient advocates, standard sets of health outcomes related to breast cancer have been determined. Furthermore, the very large incidence of breast cancer, more than 2.1 million women worldwide (156) and the clinical, psychosocial and economic intricacies associated with breast cancer care, have highlighted the significance of an integrative and comprehensive model capable of illustrating the complexity of this medical condition. Nowadays with rising healthcare costs and severe cost-cutting measures, these outcomes could enhance the effectiveness of breast cancer care and, moreover, could adjoin in future treatment decision-making or also therapeutic follow-up.

The European Health Care systems remain based on a supply-driven model instead of a patient-centered model. These systems still focus on cost-containment rather than patients’ value (159). Some European countries have attempted to implement to carry out the VBHC model adapted to their systems. Nonetheless, the absence of unanimity about which performance indicators to use, who to recompense, and how to quantify the value of encouragements to motivate greater efficiency, has retarded VBHC adoption and decreased cost and outcome collection. During the last decade, various European countries have implemented some value-based measures in their healthcare delivery. (160)

Closing inequities in Breast Cancer outcomes requires systematic advancements in outlet to quality services. The World Health Organization's Global Breast Cancer Initiative (GBCI) was created in 2021. It carries together stakeholders from around the world and across sectors with the shared aim of cutting down breast cancer by 2,5 percent per year. This would save 2,5 million lives over a 20-year period. (169 – 171)

IV-2 Recommendations

To be effective and efficient, Breast Cancer Care must be organized around patient segments with a common set of health needs. Organizing care in this way facilitates clinical teams to predict the everyday needs of patients and efficiently supply recurrently needed services, doing the routine things well. The efficiency offered by coordinating care around patient segments liberates clinicians from striving to coordinate the services that are routinely needed. The extra transmission capacity authorizes them to personalize services for individual patients who may have dissimilar needs.

Generic PROMs can be applied to analyse issues linked to Breast Cancer, and can be specifically useful for generating normative data and making benchmarks that can help in the development of new care deliveries. The downside to using generic PROMs is that they may not determine appropriate target on a main condition. Additionally, they may not be sensitive to adjustments in treatment regimens. However, cancer-specific PROMs are beneficial in diagnosing specific symptoms related to a specific type of cancer and its effect on people. Many of these are accessible in physical formats including online modules (ePRO measures), which can alleviate distress and enhance adherence to chemotherapy, as discussed at this year’s ASCO conference.

A major challenge for extensive implementation is that VBHC necessitates to be detailed at patient level’s data. It also requires digital infrastruture to handle cost and value assessment. The Nordic countries should be in an appropriate posture to match this challenge due to a high level of digitization and expanded health registers that can be connected to a scope of administrative and social data through personal ID numbers. While some academic interest in VBHC in the Nordic countries has been shown, most contributions have aimed at individual projects.

The Italian healthcare system is decentralized at both national and regional level. The high degree of regional autonomy can lead to a lack of coherence and transparency in the health services provided, or an overlapping of responsibilities. Consecutive issues of a lack of communication between centres and regions can guide to possible spoiled efforts and costs.

In France, demographic shifts and changing lifestyles are leading to substantial changes in the health of the global population, with many of the world's citizens living longer, but, in many cases, with multiple and more complex conditions. Across countries, the cost of healthcare is rising faster than economies are growing. Value, more than volume, is becoming more important. The case for countries to align their health systems with value-based approaches has perhaps never been stronger. By focusing on health outcomes, value-based healthcare (VBHC) helps healthcare providers manage cost increases, make the best use of finite resources and deliver improved care to patients.

Created in February 2019, the VBHC France Consortium is an association whose objective is to accelerate the creation of standardized registers evaluating the results of care, in other words "Le Service Médical Rendu" (SMR). The goal is to make the SMRs public for a given pathology, so that users of the health system can orient themselves and professionals can compare and improve. A first register has already been launched on cataracts. To achieve these goals, the VBHC France Consortium uses the specific cataract methodology validated by the International Consortium for Health Outcomes Measurement (ICHOM).

Unlike France, which measures indicators centred on the evaluation of good compliance with processes and not the results of the care given, foreign initiatives and evaluation systems focus more on the clinical results (CROMs) and the patient-reported quality of life outcomes (PROMs).

France and Portugal have aimed at designing a new health technology assessment (HTA) and carrying out primary health care and integrated care delivery, but the two health systems keep on moving froward. Besides, France has inserted new cost-effectiveness measures and financial inducements to stimulate the constitution of multidisciplinary teams and the employment of bundled payment systems (161, 162).

In Spain, the constant amelioration of health technology assessment and the decentralization of health administration have allowed the handing out of best practices and adaptability for innovation in regions.

Personalized Medicine should be linked to VBHC. The greatest field of promising leverage in cancer care is the growth of personalized treatments and diagnostics that can determine responder patients who have far better than standard outcomes, also prevent inappropriate drug use in non-responding patients. The diagnostic innovation is definitely not set up on categorical biomarker tests, as various tests can be applied to classify markers, and their outcomes are probable to change in terms of specificity and sensitivity.

Benchmark and transparency are fundamental

The importance of comparing the quality of care between different institutions and health professionals

The implementation of outcome indicators – PROMs and CROMs – in Breast Cancer Care within healthcare establishments allows patients to compare medical practises and their results on criteria that are important to them. This evaluation and the comparison as a result can be done at the level of a healthcare establishment, a service or a healthcare professional, depending on the relevance of the quality indicator and the medical/surgical targeted.

Two conditions must be met, such as using the same indicators, in all establishments and in the defined area, region; and guaranteeing the comparability of hospitals and the success of the care provided for each patient. Thus, that should avoid a deleterious phenomenon of selecting patients presenting the least medical risks.

However, this must be done taking into account the specificities and characteristics of each patient such as age, sex, comorbidities, medical history, socioeconomic status, etc. That impact the expected performance of a medical act for Breast Cancer Care. Undoubtedly, the most expert centres have higher rates of complications because they treat the most complex patients. It is therefore necessary to make an adjustment to the patient risk, to compare the results of care between health establishments in a objective way.

The patient must be involved in his care pathway

The development of quality indicators makes it possible to make the patient actor of his care pathway. The patient can get involved by choosing to go to a particular hospital or health professional, based on certain outcomes that are important to him.

This patient positioning as the main player in his Breast Cancer Care can also have a virtuous effect on the collection of results measured by patients. The more data patients provide, the more they strengthen their ability to choose a care facility based on relevant results.

Benchmark facilitates patient orientation in the healthcare system

The availability and publication of quality indicators, in particular the results reported by patients in terms of quality of life (PROMs) and clinical results (CROMs), developed in the healthcare system are key and should enable patients to orient themselves in the healthcare system in a logic of transparency.

Benchmark allows medical teams to question their practises, train and progress

The outcomes indicators (PROMs and CROMs) that medical teams can use will allow them to know the results of the medical practices applied in the other healthcare establishments; to use the outcomes of the quality indicators as a benchmark for comparing their practices, with those of other healthcare establishments, other healthcare professionals; and to train and exchange with other medical teams in order to improve the quality of care and thus to advance their practices. The visibility given to these results promotes the dissemination of best practices and improves the overall quality of the system (138)

Benchmark and transparency recommentadation

Here are **five reasons** why:

1. Outcomes set the purpose of the organization and define direction for its differentiation.

In 2005, Prof. Dr. Hartwig Huland launched the Martini Klinik, an innovative prostate centre in Hamburg, Germany. He hoped to offer the best care in the world to his patients. He determined “the best” pointing out “outcomes”: such as cancer recurrence rate, incontinence, erectile dysfunction. Things everyone knew were important but little measured.

2. Outcomes relate the formation of integrated care teams around the patient

This can be hard for physicians who are not used to working together, or more deleterious, who do not even like each other. However, laying out and measuring results can make up the disciplinary gap, as teams undoubtedly need to work together to accomplish better results.

3. Outcomes inspire clinicians to compare their performance and acquire knowhow from each other

The comparability of outcomes is crucial to diffuse innovations from one individual or team to another. Unsuitably, most quality measures have targeted limitedly on compliance with evidence-based processes. While such compliance is essential, it has a restricted effect on outcomes (frequently less than a quarter of the variation in outcomes is estimated to be coming from compliance with these processes). A mote complete focus on process and outcome and their synergy still exhibits occasions for improvement, from growing survival rates and long-term functioning to decreasing complications and accelerating recovery. Measuring these kinds of outcomes in a transparent and collaborative approach can be a strong achiever for improvement.

4. Outcomes highlight value-creating cost diminution

In addition to encouraging outcomes, clinical decisions likewise decide the cost of care: which medications to prescribe, which treatments to carry out, and whether or not patients should enter in acute care facilities have a critical effect on costs. The problem is that clinicians typically inflate the advantages of their care, which signifies many agreements result in high costs with poor effect on outcomes. Containing costs requires clinicians with data that can comfort them to comprehend which activities and services can be decreased or removed without putting outcomes in jeopardy.

5. Outcomes allow payment to move from volume to results.

As payment shifts from fee-for-service world to a value-based world, great results go from a noble idea to a business requirement. Paying for results and integrating payment into a bundled price will set up basically different market dynamics. It is understandable that without transparent information of their results, no provider will be able to attain success with bundled payment contracts. The ability to use PROMs filled out by patients and collected by nurses and/or physicians allows for timely and systematic assessment of clinical trends in symptoms and side effects (163).

Finally, the successful example in Breast Cancer Care in the Netherlands should help other countries implement VBHC in the comprehensive way, as defined by the Value Agenda.

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Appendix A - List of the 179 scientific articles

Authors	Title	Year	country
Robertson S., Wengström Y., Eriksen C., Sandelin K.	Breast surgeons performing immediate breast reconstruction with implants - Assessment of resource-use and patient-reported outcome measures	2012	Sweden
Kanatas A., Velikova G., Roe B., Horgan K., Ghazali N., Shaw R.J., Rogers S.N.	Patient-reported outcomes in breast oncology: A review of validated outcome instruments	2012	UK
McIntosh J., O'Donoghue J.M.	Therapeutic mammaplasty - A systematic review of the evidence	2012	UK
Eckhoff L., Knoop A.S., Jensen M.-B., Ejlertsen B., Ewertz M.,	Risk of docetaxel-induced peripheral neuropathy among 1,725 Danish patients with early stage breast cancer	2013	Denmark
Sugrue R., MacGregor G., Sugrue M., Curran S., Murphy L.	An evaluation of patient reported outcomes following breast reconstruction utilizing Breast Q	2013	Ireland
Eriksson M., Anveden L., Celebioglu F., Dahlberg K., Meldahl I., Lagergren J., Eriksen C., De Boniface J.	Radiotherapy in implant-based immediate breast reconstruction: Risk factors, surgical outcomes, and patient-reported outcome measures in a large Swedish multicenter cohort	2013	Sweden
Davis C.R., Khattak A., Cawthorn S.J., Khan U.,	Chest wall reconstruction after recurrent breast cancer using the scapular flap	2013	UK
Paget J.T., Young K.C., Wilson S.M.	Accurately costing unilateral delayed DIEP flap breast reconstruction	2013	UK

Thomson H.J., Winters Z.E., Brandberg Y., Didier F., Blazeby J.M., Mills J.	The early development phases of a European Organisation for Research and Treatment of Cancer (EORTC) module to assess patient reported outcomes (PROs) in women undergoing breast reconstruction	2013	UK
Winters Z.E., Haviland J., Balta V., Benson J., Reece-Smith A., Betambeau N.	Integration of patient-reported outcome measures with key clinical outcomes after immediate latissimus dorsi breast reconstruction and adjuvant treatment	2013	UK
Unukovych D., Johansson H., Johansson E., Arver B., Liljegren A., Brandberg Y.	Physical therapy after prophylactic mastectomy with breast reconstruction: A prospective randomized study	2014	Sweden
Mukesh M.B., Qian W., Wilkinson J.S., Dorling L., Barnett G.C., Moody A.M., Wilson C., Twyman N., Burnet N.G., Wishart G.C., Coles C.E.	Patient reported outcome measures (PROMs) following forward planned field-in field IMRT: Results from the Cambridge Breast IMRT trial	2014	UK
Korwar V., Skillman J., Matey P.	Skin reducing mastectomy and immediate reconstruction: The effect of radiotherapy on complications and patient reported outcomes	2014	UK
Rezai M., Knispel S., Kellersmann S., Lax H., Kimmig R., Kern P.	Systematization of Oncoplastic Surgery: Selection of Surgical Techniques and Patient-Reported Outcome in a Cohort of 1,035 Patients	2015	Germany
Lansu J.T.P., Essers M., Voogd A.C., Luiten E.J.T., Buijs C., Groenendaal N., Poortmans P.M.H.	The influence of simultaneous integrated boost, hypofractionation and oncoplastic surgery on cosmetic outcome and PROMs after breast conserving therapy	2015	Netherlands

Harder H., Langridge C., Solis-Trapala I., Zammit C., Grant M., Rees D., Burkinshaw L., Jenkins V.	Post-operative exercises after breast cancer surgery: Results of a RCT evaluating standard care versus standard care plus additional yoga exercise	2015	UK
Harbeck N., Iyer S., Turner N., Cristofanilli M., Ro J., André F., Loi S., Verma S., Iwata H., Bhattacharyya H., Puyana Theall K., Bartlett C.H., Loibl S.	Quality of life with palbociclib plus fulvestrant in previously treated hormone receptor-positive, HER2-negative metastatic breast cancer: Patient-reported outcomes from the PALOMA-3 trial	2016	Germany
Graf J., Simoes E., Wilicen K., Rava L., Walter C.B., Hartkopf A., Keilmann L., Taran A., Wallwiener S., Fasching P., Brucker S.Y., Wallwiener M.,	Willingness of Patients with Breast Cancer in the Adjuvant and Metastatic Setting to Use Electronic Surveys (ePRO) Depends on Sociodemographic Factors, Health-related Quality of Life, Disease Status and Computer Skills	2016	Germany
Rezai M., Strauß S., Kimmig R., Kern P.	Risk-reducing, conservative mastectomy-analysis of surgical outcome and quality of life in 272 implant-based reconstructions using TiLoop® Bra versus autologous corial flaps	2016	Germany
Teguh D.N., Bol Raap R., Struikmans H., Verhoef C., Koppert L.B., Koole A., Huang Y., van Hulst R.A.	Hyperbaric oxygen therapy for late radiation-induced tissue toxicity: Prospectively patient-reported outcome measures in breast cancer patients	2016	Netherlands
Van Verschuer V.M.T., Mureau M.A.M., Gopie J.P., Vos E.L., Verhoef C., Menke-Pluijmers M.B.E., Koppert L.B.	Patient Satisfaction and Nipple-Areola Sensitivity after Bilateral Prophylactic Mastectomy and Immediate Implant Breast Reconstruction in a High Breast Cancer Risk Population	2016	Netherlands

Brouwers P.J.A.M., van Werkhoven E., Bartelink H., Fourquet A., Lemanski C., van Loon J., Maduro J.H., Russell N.S., Scheijmans L.J.E.E., Schinagl D.A.X., Westenberg A.H., Poortmans P., Boersma L.J.	Factors associated with patient-reported cosmetic outcome in the Young Boost Breast Trial	2016	Netherlands
Kool M., van der Sijp J.R.M., Kroep J.R., Liefers G.-J., Jannink I., Guicherit O.R., Vree R., Bastiaannet E., van de Velde C.J.H., Marang-van de Mheen P.J.	Importance of patient reported outcome measures versus clinical outcomes for breast cancer patients evaluation on quality of care	2016	Netherlands
Kuijpers W., Groen W.G., Oldenburg H.S.A., Wouters M.W.J.M., Aaronson N.K., Van Harten W.H.	ehealth for breast cancer survivors: Use, feasibility and impact of an interactive portal	2016	Netherlands
da Costa F.A., Ribeiro M.C., Braga S., Carvalho E., Francisco F., Miranda A.C., Moreira A., Fallowfield L.	Sexual dysfunction in breast cancer survivors: Cross-cultural adaptation of the sexual activity questionnaire for use in Portugal [Disfunção sexual em sobreviventes de cancro da mama: Adaptação cultural do sexual activity questionnaire para uso em Portugal]	2016	Portugal
Pereira S., Fontes F., Sonin T., Dias T., Fragoso M., Castro-Lopes J.M., Lunet N.,	Chemotherapy-induced peripheral neuropathy after neoadjuvant or adjuvant treatment of breast cancer: a prospective cohort study	2016	Portugal
Maratia S., Cedillo S., Rejas J.	Assessing health-related quality of life in patients with breast cancer: a systematic and standardized comparison of available instruments using the EMPRO tool	2016	Spain

Fu M.R., Axelrod D., Guth A., Scagliola J., Rampertaap K., El Shammaa N., Fletcher J., Zhang Y., Qiu J.M., Schnabel F., Hiotis K., Wang Y., Melkus G.D.	A Web-and mobile-based intervention for women treated for breast cancer to manage chronic pain and symptoms related to lymphedema: Randomized clinical trial rationale and protocol	2016	Spain
O'Connell R.L., DiMicco R., Khabra K., O'Flynn E.A., deSouza N., Roche N., Barry P.A., Kirby A.M., Rusby J.E.	Initial experience of the BREAST-Q breast-conserving therapy module	2016	UK
Mukesh M.B., Qian W., Wah Hak C.C., Wilkinson J.S., Barnett G.C., Moody A.M., Wilson C., Coles C.E.	The Cambridge Breast Intensity-modulated Radiotherapy Trial: Comparison of Clinician- versus Patient-reported Outcomes	2016	UK
Haviland J.S., Hopwood P., Mills J., Sydenham M., Bliss J.M., Yarnold J.R., START Trialists' Group	Do Patient-reported Outcome Measures Agree with Clinical and Photographic Assessments of Normal Tissue Effects after Breast Radiotherapy? The Experience of the Standardisation of Breast Radiotherapy (START) Trials in Early Breast Cancer	2016	UK
Bjelic-Radisic V., Dorfer M., Tamussino K., Greimel E.	Patients' view of routine follow-up after breast cancer treatment	2017	Austria
Oberguggenberger A., Martini C., Huber N., Fallowfield L., Hubalek M., Daniaux M., Sperner-Unterweger B., Holzner B., Sztankay M., Gamper E., Meraner V.	Self-reported sexual health: Breast cancer survivors compared to women from the general population - an observational study	2017	Austria
Mertz B.G., Dunn-Henriksen A.K., Kroman N., Johansen C., Andersen K.G., Andersson M., Mathiesen U.B., Vibe-Petersen J., Dalton S.O., Envold Bidstrup P.	The effects of individually tailored nurse navigation for patients with newly diagnosed breast cancer: a randomized pilot study	2017	Denmark

Toyserkani N.M., Jensen C.H., Andersen D.C., Sheikh S.P., Sørensen J.A.,	Treatment of breast cancer-related lymphedema with adipose-derived regenerative cells and fat grafts: A feasibility and safety study	2017	Denmark
Nielsen H.M., Friis R.B., Linnet S., Offersen B.V.,	Loco-regional morbidity after breast conservation and axillary lymph node dissection for early breast cancer with or without regional nodes radiotherapy, perspectives in modern breast cancer treatment: the Skagen Trial 1 is active	2017	Denmark
Hurtz H.-J., Tesch H., Göhler T., Hutzschenreuter U., Harde J., Kruggel L., Jänicke M., Marschner N., TMK-Group (Tumour Registry Breast Cancer),	Persistent impairments 3 years after (neo)adjuvant chemotherapy for breast cancer: results from the MaTox project	2017	Germany
Wallwiener M., Matthies L., Simoes E., Keilmann L., Hartkopf A.D., Sokolov A.N., Walter C.B., Sickenberger N., Wallwiener S., Feisst M., Gass P., Fasching P.A., Lux M.P., Wallwiener D., Taran F.-A., Rom J., Schneeweiss A., Graf J., Brucker S.Y.	Reliability of an e-PRO Tool of EORTC QLQ-C30 for measurement of health-related	2017	Germany
Wallwiener M., Heindl F., Brucker S.Y., Taran F.-A., Hartkopf A., Overkamp F., Kolberg H.-C., Hadji P., Tesch H., Ettl J., Lux M.P., Rauh C., Blum S., Nabieva N., Brodkorb T.F., Faschingbauer C., Langemann H., Schulmeyer C., Volz B., Rübner M., Lüftner D., Müller V., Belleville E., Janni W., Fehm T.N., Wallwiener D., Ganslandt T., Beckmann M.W., Schneeweiss A., Fasching P.A., Gass P.	Implementation and Feasibility of Electronic Patient-Reported Outcome (ePRO) Data Entry in the PRAEGNANT Real-Time Advanced and Metastatic Breast Cancer Registry	2017	Germany
Hartkopf A.D., Graf J., Simoes E., Keilmann L., Sickenberger N., Gass P., Wallwiener D., Matthies L., Taran F.-A., Lux M.P., Wallwiener S., Belleville E., Sohn C., Fasching P.A., Schneeweiss A., Brucker S.Y., Wallwiener M.,	Electronic-based patient-reported outcomes:willingness, needs, and barriers in adjuvant and metastatic breast cancer patients	2017	Germany

Stefanovic S., Wallwiener M., Karic U., Domschke C., Katic L., Taran F.-A., Pesic A., Hartkopf A., Hadji P., Teufel M., Schuetz F., Sohn C., Fasching P., Schneeweiss A., Brucker S.	Patient-reported outcomes (PRO) focused on adverse events (PRO-AEs) in adjuvant and metastatic breast cancer: clinical and translational implications	2017	Germany
Lagendijk M., Vos E.L., Koning A.H.J., Hunink M.G.M., Pignol J.P., Corten E.M.L., de Monye C., van Deurzen C.H.M., van Dam J.H., Vrijland W.W., Contant C.M.E., Verhoef C., van Lankeren W., Koppert L.B.,	TUmor-volume to breast-volume RAtio for improving COSmetic results in breast cancer patients (TURACOS) a randomized controlled trial	2017	Netherlands
Volders J.H., Haloua M.H., Krekel N.M.A., Negenborn V.L., Kolk R.H.E., Lopes Cardozo A.M.F., Bosch A.M., de Widt-Levert L.M., van der Veen H., Rijna H., Taets van Amerongen A.H.M., Jóźwiak K., Meijer S., van den Tol M.P.	Intraoperative ultrasound guidance in breast-conserving surgery shows superiority in oncological outcome, long-term cosmetic and patient-reported outcomes: Final outcomes of a randomized controlled trial (COBALT)	2017	Netherlands
Harfouche A., Silva S., Faria J., Araújo R., Gouveia A., Lacerda M., D’Orey L.,	Breast cancer: Value-based healthcare, costs and financing [Cancro de mama: Valor em saúde, custos e financiamento]	2017	Portugal
Thorarinsson A., Fröjd V., Kölby L., Ljungdal J., Taft C., Mark H.	Long-Term Health-Related Quality of Life after Breast Reconstruction: Comparing 4 Different Methods of Reconstruction	2017	Sweden
Browall M., Brandberg Y., Nasic S., Rydberg P., Bergh J., Rydén A., Xie H., Eriksson I., Wengström Y.,	A prospective exploration of symptom burden clusters in women with breast cancer during chemotherapy treatment	2017	Sweden
Unukovych D., Johansson H., Brandberg Y.,	Preoperative psychosocial characteristics may predict body image and sexuality two years after risk-reducing mastectomy: A prospective study	2017	Sweden

Khajuria A., Smith O.J., Prokopenko M., Greenfield M., Mosahebi A.	Protocol for a systematic review and meta-analysis on the clinical outcomes and cost of deep inferior epigastric perforator (DIEP) flap versus implants for breast reconstruction	2017	UK
Matthews H., Carroll N., Renshaw D., Turner A., Park A., Skillman J., McCarthy K., Grunfeld E.A.	Predictors of satisfaction and quality of life following post-mastectomy breast reconstruction	2017	UK
Harcourt D., Paraskeva N., White P., Powell J., Clarke A.	A study protocol of the effectiveness of PEGASUS: A multi-centred study comparing an intervention to promote shared decision making about breast reconstruction with treatment as usual	2017	UK
Di Micco R., O'Connell R.L., Barry P.A., Roche N., MacNeill F.A., Rusby J.E.,	Standard wide local excision or bilateral reduction mammoplasty in large-breasted women with small tumours: Surgical and patient-reported outcomes	2017	UK
Di Micco R., O'Connell R.L., Barry P.A., Roche N., MacNeill F.A., Rusby J.E.	Bilateral mammoplasty for cancer: Surgical, oncological and patient-reported outcomes	2017	UK
Oberguggenberger A., Meraner V., Sztankay M., Hilbert A., Hubalek M., Holzner B., Gamper E., Kemmler G., Baumgartner T., Lackinger I., Sperner-Unterweger B., Mangweth-Matzek B.	Health Behavior and Quality of Life Outcome in Breast Cancer Survivors: Prevalence Rates and Predictors	2018	Austria
Juhl A.A., Redsted S., Engberg Damsgaard T.	Autologous fat grafting after breast conserving surgery: Breast imaging changes and patient-reported outcome	2018	Denmark
Møller P.K., Olling K., Berg M., Habæk I., Haislund B., Iversen A.-M., Ewertz M., Lorenzen E.L., Brink C.	Breast cancer patients report reduced sensitivity and pain using a barrier film during radiotherapy – A Danish intra-patient randomized multicentre study	2018	Denmark

Karsten M.M., Speiser D., Hartmann C., Zeuschner N., Lippold K., Kiver V., Gocke P., Kirchberger V., Blohmer J.-U.	Web-based patient-reported outcomes using the international consortium for health outcome measurement dataset in a major german university hospital: Observational study	2018	Germany
Thronicke A., Kröz M., Merkle A., Matthes H., Herbstreit C., Schad F.	Psychosocial, Cognitive, and Physical Impact of Elaborate Consultations and Life Review in Female Patients with Non-Metastasized Breast Cancer	2018	Germany
Hurley C.M., McArdle A., Joyce K.M., O'broin E.	Skin-sparing mastectomy with immediate nipple reconstruction during autologous latissimus dorsi breast reconstruction: A review of patient satisfaction	2018	Ireland
Casella D., Di Taranto G., Marcasciano M., Sordi S., Kothari A., Kovacs T., Lo Torto F., Cigna E., Ribuffo D., Calabrese C.	Nipple-sparing bilateral prophylactic mastectomy and immediate reconstruction with TiLoop® Bra mesh in BRCA1/2 mutation carriers: A prospective study of long-term and patient reported outcomes using the BREAST-Q	2018	Italy
Beugels J., Kool M., Hoekstra L.T., Heuts E.M., Tuinder S.M.H., Van Der Hulst R.R.W.J., Piatkowski A.	Quality of Life of Patients after Immediate or Delayed Autologous Breast Reconstruction: A Multicenter Study	2018	Netherlands
Lagendijk M., van Egdom L.S.E., van Veen F.E.E., Vos E.L., Mureau M.A.M., van Leeuwen N., Hazelzet J.A., Lingsma H.F., Koppert L.B.,	Patient-Reported Outcome Measures May Add Value in Breast Cancer Surgery	2018	Netherlands
Melissant H.C., Verdonck-de Leeuw I.M., Lissenberg-Witte B.I., Konings I.R., Cuijpers P., Van Uden-Kraan C.F.,	'Oncokompas', a web-based self-management application to support patient activation and optimal supportive care: a feasibility study among breast cancer survivors	2018	Netherlands
Lagendijk M., van Egdom L.S.E., Richel C., van Leeuwen N., Verhoef C., Lingsma H.F., Koppert L.B.	Patient reported outcome measures in breast cancer patients	2018	Netherlands
Lagendijk M., Vos E.L., Nieboer D., Verhoef C., Corten E.M.L., Koppert L.B.	Evaluation of cosmetic outcome following breast-conserving therapy in trials: panel versus digitalized analysis and the role of PROMs	2018	Netherlands

Jacobs D.H.M., Speijer G., Petoukhova A.L., Roeloffzen E.M.A., Straver M., Marinelli A., Fisscher U., Zwanenburg A.G., Merkus J., Marijnen C.A.M., Mast M.E., Koper P.C.M.,	Acute toxicity of intraoperative radiotherapy and external beam-accelerated partial breast irradiation in elderly breast cancer patients	2018	Netherlands
Catsman C.J.L.M., Beek M.A., Voogd A.C., Mulder P.G.H., Luiten E.J.T.	The COSMAM TRIAL a prospective cohort study of quality of life and cosmetic outcome in patients undergoing breast conserving surgery	2018	Netherlands
Gregorowitsch M.L., van den Bongard H.J.G.D., Young-Afat D.A., Pignol J.P., van Gils C.H., May A.M., Verkooijen H.M.,	Severe depression more common in patients with ductal carcinoma in situ than early-stage invasive breast cancer patients	2018	Netherlands
Brouwers P.J.A.M., van Loon J., Houben R.M.A., Paulissen J., Engelen S.M.E., Heuts M., de Boer M., Verhoeven K., De Ruysscher D., Boersma L.J.	Are PROMs sufficient to record late outcome of breast cancer patients treated with radiotherapy? A comparison between patient and clinician reported outcome through an outpatient clinic after 10 years of follow up	2018	Netherlands
García-Gutierrez S., Orive M., Sarasqueta C., Legarreta M.J., Gonzalez N., Redondo M., Rivero A., Serrano-Aguilar P., Castells X., Quintana J.M., Sala M.	Health services research in patients with breast cancer (CAMISS-prospective): Study protocol for an observational prospective study	2018	Spain
Bhattacharya I.S., Haviland J.S., Kirby A.M., Kirwan C.C., Hopwood P., Yarnold J.R., Bliss J.M., Coles C.E.	Patient-reported outcomes over 5 years after whole- Or partial-breast radiotherapy: Longitudinal analysis of the import low (CRUK/ 06/003) phase III randomized controlled trial	2018	UK
Powell-Brett S., Goh S.	Clinical and patient reported outcomes in breast reconstruction using acellular dermal matrix	2018	UK
Kazzazi F., Haggie R., Forouhi P., Kazzazi N., Wyld L., Malata C.M.	A comparison of patient satisfaction (using the BREAST-Q questionnaire) with bilateral breast reconstruction following risk-reducing or therapeutic mastectomy	2018	UK
Hu J., Rainsbury R.M., Segaran A., Predescu O., Roy P.G.,	Objective assessment of clinical, oncological and cosmetic outcomes following volume replacement in patients undergoing oncoplastic breast-conserving surgery: Protocol for a systematic review	2018	UK

Mills J., Haviland J.S., Moynihan C., Bliss J.M., Hopwood P., the START Trial Management Group	Women's Free-text Comments on their Quality of Life: An Exploratory Analysis from the UK Standardisation of Breast Radiotherapy (START) Trials for Early Breast Cancer	2018	UK
Jeffs E., Ream E., Taylor C., Bick D.	Clinical effectiveness of decongestive treatments on excess arm volume and patient-centered outcomes in women with early breast cancer-related arm lymphedema: a systematic review	2018	UK
Liu L.Q., Branford O.A., Mehigan S.	BREAST-Q measurement of the patient perspective in oncoplastic breast surgery: A systematic review	2018	UK
Kindts I., Laenen A., van den Akker M., Weltens C.,	PROMs following breast-conserving therapy for breast cancer: results from a prospective longitudinal monocentric study	2019	Belgium
Kindts I., Laenen A., Christiaens M., Janssen H., Van Limbergen E., Weltens C.	Comparison of brachytherapy and external beam radiotherapy boost in breast-conserving therapy: Patient-reported outcome measures and aesthetic outcome [Vergleich von Brachytherapie und perkutaner Boost-Strahlentherapie nach brusterhaltender Therapie: Patientenbewertung und ästhetisches Ergebnis]	2019	Belgium
Bæksted C.W., Nissen A., Knoop A.S., Pappot H.,	Patients' experience of communication and handling of symptomatic adverse events in breast cancer patients receiving adjuvant chemotherapy	2019	Denmark
Saltbæk L., Karlsen R.V., Bidstrup P.E., Høeg B.L., Zoffmann V., Horsbøl T.A., Holländer N.H., Svendsen M.N., Christensen H.G., Dalton S.O., Johansen C.	MyHealth: specialist nurse-led follow-up in breast cancer. A randomized controlled trial–development and feasibility	2019	Denmark
Ammitzbøll G., Kristina Kjær T., Johansen C., Lanng C., Wreford Andersen E., Kroman N., Zerahn B., Hyldegaard O., Envold Bidstrup P., Oksbjerg Dalton S.	Effect of progressive resistance training on health-related quality of life in the first year after breast cancer surgery–results from a randomized controlled trial	2019	Denmark

Pappot H., Bæksted C., Knoop A., Mitchell S.A., Nissen A., Johansen C.,	Routine surveillance for symptomatic toxicities with real-time clinician reporting in Danish breast cancer patients—Organization and design of the first national, cluster randomized trial using the Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events (PRO-CTCAE)	2019	Denmark
Toyserkani N.M., Jensen C.H., Tabatabaeifar S., Jørgensen M.G., Hvidsten S., Simonsen J.A., Andersen D.C., Sheikh S.P., Sørensen J.A.,	Adipose-derived regenerative cells and fat grafting for treating breast cancer-related lymphedema: Lymphoscintigraphic evaluation with 1 year of follow-up	2019	Denmark
Lagrange A., Decoux D., Briot N., Hennequin A., Coudert B., Desmoulins I., Bertaut A.,	Visceral osteopathic manipulative treatment reduces patient reported digestive toxicities induced by adjuvant chemotherapy in breast cancer: A randomized controlled clinical study	2019	France
Carayol M., Ninot G., Senesse P., Bleuse J.-P., Gourgou S., Sancho-Garnier H., Sari C., Romieu I., Romieu G., Jacot W.,	Short- and long-term impact of adapted physical activity and diet counseling during adjuvant breast cancer therapy: The "aPAD1" randomized controlled trial	2019	France
Feißt M., Heil J., Stolpner I., von Au A., Domschke C., Sohn C., Kieser M., Rauch G., Hennigs A.	Psychometric validation of the Breast Cancer Treatment Outcome Scale (BCTOS-12): a prospective cohort study	2019	Germany
Stolpner I., Heil J., Feißt M., Karsten M.M., Weber W.P., Blohmer J.-U., Forster T., Golatta M., Schütz F., Sohn C., Hennigs A.,	Clinical Validation of the BREAST-Q Breast-Conserving Therapy Module	2019	Germany
Schmidt M.E., Scherer S., Wiskemann J., Steindorf K.	Return to work after breast cancer: The role of treatment-related side effects and potential impact on quality of life	2019	Germany

Matthies L.M., Taran F.-A., Keilmann L., Schneeweiss A., Simoes E., Hartkopf A.D., Sokolov A.N., Walter C.B., Sickenberger N., Wallwiener S., Feisst M., Gass P., Lux M.P., Schuetz F., Fasching P.A., Sohn C., Brucker S.Y., Graf J., Wallwiener M.	An electronic patient-reported outcome tool for the FACT-B (Functional assessment of cancer therapy-breast) Questionnaire for measuring the health-related quality of life in patients with breast cancer: Reliability study	2019	Germany
Casella D., Di Taranto G., Marcasciano M., Lo Torto F., Barellini L., Sordi S., Gaggelli I., Roncella M., Calabrese C., Ribuffo D.	Subcutaneous expanders and synthetic mesh for breast reconstruction: Long-term and patient-reported BREAST-Q outcomes of a single-center prospective study	2019	Italy
van Egdom L.S.E., Oemrawsingh A., Verweij L.M., Lingsma H.F., Koppert L.B., Verhoef C., Klazinga N.S., Hazelzet J.A.,	Implementing Patient-Reported Outcome Measures in Clinical Breast Cancer Care: A Systematic Review	2019	Netherlands
de Ligt K.M., Heins M., Verloop J., Smorenburg C.H., Korevaar J.C., Siesling S.,	Patient-reported health problems and healthcare use after treatment for early-stage breast cancer	2019	Netherlands
van Egdom L.S.E., Lagendijk M., van der Kemp M.H., van Dam J.H., Mureau M.A.M., Hazelzet J.A., Koppert L.B.,	Implementation of Value Based Breast Cancer Care	2019	Netherlands
Gregorowitsch M.L., Ghedri A., Young-Afat D.A., Bijlsma R., Baas I.O., van Schaik-van de Mheen C., Agterof M.J., Göker E., ten Bokkel Huinink D., van den Bongard H.J.G.D., Verkooijen H.M., UMBRELLA study group	The effect of chemotherapy on subjective cognitive function in younger early-stage breast cancer survivors treated with chemotherapy compared to older patients	2019	Netherlands
Brands-Appeldoorn A., Maaskant-Braat S., Schenk K., Roumen R.	Cosmetic Consequences of Breast-Conserving Treatment for Breast Cancer: Something Worth Talking About	2019	Netherlands

Gregorowitsch M.L., Verkooijen H.M., Houweling A., Fuhler N., Koelemij R., Schoenmaeckers E.J.P., Sier M.F., Ernst M.F., Witkamp A.J., Van Dalen T., Young-Afat D.A., van den Bongard D.H.J.G., UMBRELLA study group	Impact of modern-day axillary treatment on **patient reported** arm morbidity and physical functioning in breast cancer patients	2019	Netherlands
Kouwenberg C.A.E., Kranenburg L.W., Visser M.S., Busschbach J.J., Mureau M.A.M.	"The validity of the EQ-5D-5L in measuring quality of life benefits of breast reconstruction"	2019	Netherlands
Skraastad B.K., Knudsen C., Jackson C., Utheim T.P., Pripp A.H., Tønseth K.A.	Quality of life, patient satisfaction and cosmetic outcome after delayed breast reconstruction using DIEP flap: a 10 years' follow-up survey	2019	Norway
Tan A.C., McCrary J.M., Park S.B., Trinh T., Goldstein D.	Chemotherapy-induced peripheral neuropathy—patient-reported outcomes compared with NCI-CTCAE grade	2019	Portugal
Ferreira A.R., Di Meglio A., Pistilli B., Gbenou A.S., El-Mouhebb M., Dauchy S., Charles C., Joly F., Everhard S., Lambertini M., Coutant C., Cottu P., Lerebours F., Petit T., Dalenc F., Rouanet P., Arnaud A., Martin A., Berille J., Ganz P.A., Partridge A.H., Delaloge S., Michiels S., Andre F., Vaz-Luis I.,	Differential impact of endocrine therapy and chemotherapy on quality of life of breast cancer survivors: a prospective patient-reported outcomes analysis	2019	Portugal
Sousa H., Castro S., Abreu J., Pereira M.G.,	A systematic review of factors affecting quality of life after postmastectomy breast reconstruction in women with breast cancer	2019	Portugal
Lindegren A., Schultz I., Wickman M.,	Improved patient-reported outcomes after autologous fat transplantation and corrective surgery after breast surgery	2019	Sweden
Critchley A.C., Cain H.J.	Surgical techniques in breast cancer: an overview	2019	UK

Warrington L., Absolom K., Holch P., Gibson A., Clayton B., Velikova G.,	Online tool for monitoring adverse events in patients with cancer during treatment (eRAPID): Field testing in a clinical setting	2019	UK
Galalae R., Hannoun-Lévi J.-M.	Accelerated partial breast irradiation by brachytherapy: Present evidence and future developments	2020	Austria
Bjelic-Radisic V., Fitzal F., Knauer M., Steger G., Egle D., Greil R., Schrenk P., Balic M., Singer C., Exner R., Soelkner L., Gnant M.,	Primary surgery versus no surgery in synchronous metastatic breast cancer: Patient-reported quality-of-life outcomes of the prospective randomized multicenter ABCSG-28 Posytive Trial	2020	Austria
Møller T., Andersen C., Lillelund C., Bloomquist K., Christensen K.B., Ejlertsen B., Tuxen M., Oturai P., Breitenstein U., Kolind C., Travis P., Bjerg T., Rørth M., Adamsen L.,	Physical deterioration and adaptive recovery in physically inactive breast cancer patients during adjuvant chemotherapy: a randomised controlled trial	2020	Denmark
Riis C.L., Jensen P.T., Bechmann T., Möller S., Coulter A., Steffensen K.D.,	Satisfaction with care and adherence to treatment when using patient reported outcomes to individualize follow-up care for women with early breast cancer–a pilot randomized controlled trial	2020	Denmark
Rose M., Svensson H., Handler J., Hoyer U., Ringberg A., Manjer J.,	Patient-reported outcome after oncoplastic breast surgery compared with conventional breast-conserving surgery in breast cancer	2020	Denmark
Cottu P., Coudert B., Perol D., Doly A., Manson J., Aujoulat O., Barletta H., Chalabi N., Samelson L., Pivot X.	Evolution in the real-world therapeutic strategies in more than 20,000 women with breast cancer having received human epidermal growth factor receptor 2–targeted treatments: Results from the french personalized reimbursement model database (2011–2018)	2020	France
Kühn F., Blohmer J.-U., Karsten M.M.	Intraoperative indocyanine green fluorescence imaging in breast surgery	2020	Germany

Stangl S., Haas K., Eichner F.A., Grau A., Selig U., Ludwig T., Fehm T., Stüber T., Rashid A., Kerscher A., Bargou R., Hermann S., Arndt V., Meyer M., Wildner M., Faller H., Schrauder M.G., Weigel M., Schlembach U., Heuschmann P.U., Wöckel A.	Development and proof-of-concept of a multicenter, patient-centered cancer registry for breast cancer patients with metastatic disease - The ""breast cancer care for patients with metastatic disease"" (BRE-4-MED) registry	2020	Germany
Oei S.L., Thronicke A., Kröz M., von Trott P., Schad F., Matthes H.,	Impact of Oncological Therapy and Viscum album L Treatment on Cancer-Related Fatigue and Internal Coherence in Nonmetastasized Breast Cancer Patients	2020	Germany
Rocco N., Papallo I., Nava M.B., Catanuto G., Accurso A., Onofrio I., Oliviero O., Improta G., Speranza D., Domingos M., Russo T., de Santis R., Martorelli M., Gloria A.	Additive manufacturing and technical strategies for improving outcomes in breast reconstructive surgery	2020	Italy
Divella M., Vetrugno L., Bertozzi S., Seriau L., Cedolini C., Bove T.	Patient-reported pain and other symptoms among breast cancer survivors: prevalence and risk factors	2020	Italy
Ghilli M., Mariniello M.D., Camilleri V., Murante A.M., Ferrè F., Colizzi L., Gennaro M., Caligo M.A., Scatena C., Del Re M., Nuti S., Caramella D., Roncella M.	PROMs in post-mastectomy care: Patient self-reports (BREAST-Q™) as a powerful instrument to personalize medical services	2020	Italy
Batenburg M.C.T., van den Bongard H.J.G.D., Kleynen C.E., Maarse W., Witkamp A., Ernst M., Doeksen A., van Dalen T., Sier M., Schoenmaeckers E.J.P., Baas I.O., Verkooijen H.M.,	Assessing the effect of hyperbaric oxygen therapy in breast cancer patients with late radiation toxicity (HONEY trial): a trial protocol using a trial within a cohort design	2020	Netherlands
Van De Voort E.M.F., Klem T.M.A.L., Struik G.M., Birnie E., Sinke R.H.J.A., Ghandi A.	Patient reported cosmetic outcome after vacuum assisted excision of benign breast lesions: A cross-sectional study	2020	Netherlands

Miseré R., Schop S., Heuts E., de Grzymala A.P., van der Hulst R.	Psychosocial well-being at time of diagnosis of breast cancer affects the decision whether or not to undergo breast reconstruction	2020	Netherlands
Reinders F.C.J., Young-Afat D.A., Batenburg M.C.T., Bruekers S.E., van Amerongen E.A., Macaré van Maurik J.F.M., Braakenburg A., Zonnevylle E., Hoefkens M., Teunis T., Verkooijen H.M., van den Bongard H.J.G.D., Maarse W.	Higher reconstruction failure and less patient-reported satisfaction after post mastectomy radiotherapy with immediate implant-based breast reconstruction compared to immediate autologous breast reconstruction	2020	Netherlands
van Egdom L.S.E., de Kock M.A., Apon I., Mureau M.A.M., Verhoef C., Hazelzet J.A., Koppert L.B.,	Patient-Reported Outcome Measures may optimize shared decision-making for cancer risk management in BRCA mutation carriers	2020	Netherlands
Vasmel J.E., Charaghvandi R.K., Houweling A.C., Philippens M.E.P., van Asselen B., Vreuls C.P.H., van Diest P.J., van Leeuwen A.M.G., van Gorp J., Witkamp A.J., Koelemij R., Doeksen A., Sier M.F., van Dalen T., van der Wall E., van Dam I., Veldhuis W.B., Kirby A.M., Verkooijen H.M., van den Bongard H.J.G.D.,	Tumor Response After Neoadjuvant Magnetic Resonance Guided Single Ablative Dose Partial Breast Irradiation	2020	Netherlands
Batenburg M.C.T., Gregorowitsch M.L., Maarse W., Witkamp A., Young-Afat D.A., Braakenburg A., Doeksen A., van Dalen T., Sier M., Schoenmaeckers E.J.P., van Gils C.H., van den Bongard H.J.G.D., Verkooijen H.M., the UMBRELLA study group	Patient-reported cosmetic satisfaction and the long-term association with quality of life in irradiated breast cancer patients	2020	Netherlands
Moreira I.C., Ventura S.R., Ramos I., Fougo J.L., Rodrigues P.P.	Preoperative localisation techniques in breast conservative surgery: A systematic review and meta-analysis	2020	Portugal

Kuhar C.G., Cepeda T.G., Kovač T., Kukar M., Gorenjec N.R.	Mobile app for symptom management and associated quality of life during systemic treatment in early stage breast cancer: Nonrandomized controlled prospective cohort study	2020	Slovenia
Hernanz F., Jimeno J., Muñoz P., Diaz S.	Patient-reported outcomes following breast-conserving treatment using BREAST-Q questionnaire	2020	Spain
Lohmander F., Lagergren J., Johansson H., Roy P.G., Frisell J., Brandberg Y.	Quality of life and patient satisfaction after implant-based breast reconstruction with or without acellular dermal matrix: randomized clinical trial	2020	Sweden
Fjell M., Langius-Eklöf A., Nilsson M., Wengström Y., Sundberg K.	Reduced symptom burden with the support of an interactive app during neoadjuvant chemotherapy for breast cancer – A randomized controlled trial	2020	Sweden
van Egdom L.S.E., Pusic A., Verhoef C., Hazelzet J.A., Koppert L.B.	Machine learning with PROs in breast cancer surgery caution: Collecting PROs at baseline is crucial	2020	Sweden
Elfgen C., Güth U., Gruber G., Birrer S., Bjelic-Radisic V., Fleisch M., Tausch C.J.	Breast-conserving surgery with intraoperative radiotherapy in recurrent breast cancer: the patient's perspective	2020	Switzerland
Harris J., Purssell E., Cornelius V., Ream E., Jones A., Armes J.,"Anxiety	Development and internal validation of a predictive risk model for anxiety after completion of treatment for early stage breast cancer	2020	UK
Harvey K.L., Mills N., White P., Holcombe C., Potter S.,	The Pre-BRA (pre-pectoral Breast Reconstruction EvAluation) feasibility study: Protocol for a mixed-methods IDEAL 2a/2b prospective cohort study to determine the safety and effectiveness of prepectoral implant-based breast reconstruction	2020	UK

Lidington E., McGrath S.E., Noble J., Stanway S., Lucas A., Mohammed K., Van Der Graaf W., Husson O.	Evaluating a digital tool for supporting breast cancer patients: A randomized controlled trial protocol (ADAPT)	2020	UK
Laustsen-Kiel C.M., Lauritzen E., Langhans L., Engberg Damsgaard T.,	Study protocol for a 10-year prospective observational study, examining lymphoedema and patient-reported outcome after breast reconstruction	2021	Denmark
Høeg B.L., Saltbæk L., Christensen K.B., Karlsen R.V., Johansen C., Dalton S.O., Bennett A., Bidstrup P.E.	The development and initial validation of the Breast Cancer Recurrence instrument (BreastCaRe)—a patient-reported outcome measure for detecting symptoms of recurrence after breast cancer	2021	Denmark
Pappot H., Baeksted C.W., Nissen A., Knoop A., Mitchell S.A., Christensen J., Hjollund N.H., Johansen C.	Clinical effects of assessing electronic patient-reported outcomes monitoring symptomatic toxicities during breast cancer therapy: a nationwide and population-based study	2021	Denmark
Buch-Larsen K., Lund-Jacobsen T., Andersson M., Schwarz P.,	Weight change in post-menopausal women with breast cancer during chemotherapy—perspectives on nutrition, activity and bone metabolism: An interim analysis of a 5-year prospective cohort	2021	Denmark
Riis C.L., Stie M., Bechmann T., Jensen P.T., Coulter A., Möller S., Steffensen K.D.,	ePRO-based individual follow-up care for women treated for early breast cancer: impact on service use and workflows	2021	Denmark
Nielsen A.W.M., Lundorff M., Nielsen H.M., Alsner J., Vrou Offersen B., Kristensen M.H., Zachariae R.	Symptom trajectories in breast cancer survivors: growth mixture analysis of patient-reported pain, fatigue, insomnia, breast and arm symptoms	2021	Denmark
Nielsen A.W.M., Kristensen M.H., Offersen B.V., Alsner J., Zachariae R., Nielsen H.M.	Patient-reported outcomes in postmenopausal breast cancer survivors–comparisons with normative data	2021	Denmark

Rautalin M., Jahkola T., Roine R.P.	Surgery and health-related quality of life – A prospective follow up study on breast cancer patients in Finland	2021	Finland
Takala L., Kuusinen T.-E., Skyttä T., Kellokumpu-Lehtinen P.-L., Bärlund M.,	Electronic Patient-reported Outcomes During Breast Cancer Adjuvant Radiotherapy	2021	Finland
Majou D., Mekarnia Y., Martin B., Rouzier R., Héquet D.,	Episode-based bundled payment model: evaluation of medical costs for early operable breast cancer [Financement à l'épisode de soins: évaluation du coût d'une chirurgie première pour cancer du sein précoce]	2021	France
Lapidari P., Gbenou A., Havas J., Martin E., Pistilli B., Martin A.-L., Everhard S., Coutant C., Cottu P., Lesur A., Lerebours F., Tredan O., Vanlemmens L., Jouannaud C., Levy C., Rigal O., Fournier M., Andre F., Vaz-Luis I., Di Meglio A.,	Long-term patient reported outcomes and hematologic toxicity among patients who received Granulocyte-Colony Stimulating Factors during chemotherapy for early breast cancer	2021	France
Karsten M.M., Kühn F., Pross T., Blohmer J.-U., Hage A.M., Fischer F., Rose M., Grittner U., Gebert P., Ferencz J., Pauler L., Breidenbach C., Kowalski C., Matthesius G., Seemann J., Lenz J., Rocabado S., Du Bois M., Straubing L., on behalf of the PRO B Steering Board,	PRO B: evaluating the effect of an alarm-based patient-reported outcome monitoring compared with usual care in metastatic breast cancer patients—study protocol for a randomised controlled trial	2021	Germany
Stolpner I., Heil J., Riedel F., Wallwiener M., Schäfgen B., Feißt M., Golatta M., Hennigs A.	Long-Term Patient Satisfaction and Quality of Life After Breast-Conserving Therapy: A Prospective Study Using the BREAST-Q	2021	Germany
Lindberg-Scharf P., Steinger B., Koller M., Hofstädter A., Ortmann O., Kurz J., Sasse J., Klinkhammer-Schalke M.,	Long-term improvement of quality of life in patients with breast cancer: supporting patient-physician communication by an electronic tool for inpatient and outpatient care	2021	Germany

Lee K., Norris M.K., Wang E., Dieli-Conwright C.M.	Effect of high-intensity interval training on patient-reported outcomes and physical function in women with breast cancer receiving anthracycline-based chemotherapy	2021	Germany
Blohmer J.-U., Beier L., Faridi A., Ankel C., Krause-Bergmann B., Paepke S., Mau C., Keller M., Strittmatter H.J., Karsten M.M.,	Patient-reported outcomes and aesthetic results after immediate breast reconstruction using human acellular dermal matrices: Results of a multicenter, prospective, observational NOGGO-AWOGyn study	2021	Germany
Dürr P., Schlichtig K., Kelz C., Deutsch B., Maas R., Eckart M.J., Wilke J., Wagner H., Wolff K., Preuß C., Brückl V., Meidenbauer N., Staerk C., Mayr A., Fietkau R., Goebell P.J., Kunath F., Beckmann M.W., MacKensen A., Neurath M.F., Pavel M., Dörje F., Fromm M.F.	The Randomized AMBORA Trial: Impact of Pharmacological/Pharmaceutical care on medication safety and patient-reported outcomes during treatment with new oral anticancer agents	2021	Germany
Schmidt M., Steindorf K.,	Quality of life after breast cancer: Assessment, relevance and effective interventions [Lebensqualität nach Brustkrebs: Erfassung, Relevanz und effektive Interventionen]	2021	Germany
Salgarello M., Pagliara D., Barone Adesi L., Visconti G., Wild J.B., Matey P.,	Direct to Implant Breast Reconstruction With Prepectoral Micropolyurethane Foam-Coated Implant: Analysis of Patient Satisfaction	2021	Italy
Innocenti A., Melita D., Affortunati M., Susini T., Innocenti M.,	Immediate-implant-based-breast-reconstruction with two-stage expander-implant reconstruction versus one-stage-reconstruction with acellular dermal matrix: Analysis of patients' satisfaction	2021	Italy
Casella D., Lo Torto F., Marcasciano M., Barellini L., Frattaroli J.M., Turriziani G., Ribuffo D.	Breast Animation Deformity: A Retrospective Study on Long-Term and Patient-Reported Breast-Q Outcomes	2021	Italy

Ferrè F., De Rosis S., Murante A.M., Gilmore K.J., Ghilli M., Mariniello D., Nuti S., Roncella M.	Systematic and continuous collection of patient-reported outcomes and experience in women with cancer undergoing mastectomy and immediate breast reconstruction: a study protocol for the Tuscany Region (Italy)	2021	Italy
van Cappellen-van Maldegem S.J.M., Mols F., Horevoorts N., de Kruif A., Buffart L.M., Schoormans D., Trompetter H., Beijer S., Ezendam N.P.M., de Boer M., Winkels R., Kampman E., Schuit J., van de Poll-Franse L., Seidell J.C., Hoedjes M.	Towards OPtimal TIming and Method for promoting sUstained adherence to lifestyle and body weight recommendations in postMenopausal breast cancer survivors (the OPTIMUM-study): protocol for a longitudinal mixed-method study	2021	Netherlands
van der Plas-Krijgsman W.G., de Boer A.Z., de Jong P., Bastiaannet E., van den Bos F., Mooijaart S.P., Liefers G.J., Portielje J.E.A., de Glas N.A.	Predicting disease-related and patient-reported outcomes in older patients with breast cancer - a systematic review	2021	Netherlands
Clarijs M.E., Thurell J., Kühn F., Uyl-De Groot C.A., Hedayati E., Karsten M.M., Jager A., Koppert L.B.	Measuring quality of life using patient-reported outcomes in real-world metastatic breast cancer patients: The need for a standardized approach	2021	Netherlands
Schop S.J., Joosen M.E.M., Wolswijk T., Heuts E.M., van der Hulst R.R.W.J., Piatkowski de Grzymala A.A.	Quality of life after autologous fat transfer additional to prosthetic breast reconstruction in women after breast surgery: A systematic review: QoL after AFT: a review	2021	Netherlands
Filipe M.D., Simons J.M., Moeliker L., Waaijer L., Vriens M.R., van Diest P.J., Witkamp A.J.	Patient-reported outcomes of ductoscopy procedures for pathologic nipple discharge	2021	Netherlands
Lopes-Conceicao L., Brandao M., Araujo N., Severo M., Dias T., Peleteiro B., Fontes F., Pereira S., Lunet N.	Quality of life trajectories during the first three years after diagnosis of breast cancer: The NEON-BC study	2021	Portugal

Avino A., Gheoca-Mutu D.E., Raducu L., Nedelea S.A., Jecan C.R., Lascar I.	Patient-reported quality of life 3 months after breast reconstruction	2021	Romania
Sjökvist O., Håkansson S., Pantiora E., Karakatsanis A.,	Challenging the current norm: Does health related quality of life data from reference populations accurately reflect baseline values in breast cancer patients? An observational cohort study comparing EORTC QLQ-C30 scores between the general Swedish population and baseline scores in breast cancer patients	2021	Sweden
Lohmander F., Lagergren J., Johansson H., Roy P.G., Brandberg Y., Frisell J.,	Effect of immediate implant-based breast reconstruction after mastectomy with and without acellular dermal matrix among women with breast cancer: A randomized clinical trial	2021	Sweden
Aliotta R.E., Duraes E.F.R., Scomacao I., Morisada M., Orra S., Moreira A., Bernard S., Schwarz G., Djohan R.,	A controlled cost and outcomes analysis of acellular dermal matrix and implant-based reconstruction	2021	Sweden
Bergqvist J., Lundström S., Wengström Y.	Patient interactive digital support for women with adjuvant endocrine therapy in order to increase compliance and quality of life	2021	Sweden
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