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Complete List of Authors:	van Veghel, Willem; Franciscus Gasthuis en Vlietland, Finance and Control van Dijk, Suzanne; Franciscus Gasthuis en Vlietland, Department of Geriatrics Klem, Taco; Franciscus Gasthuis en Vlietland, Breast Clinic Weel, Angelique; Maasstad Hospital, Department of Rheumatology; Erasmus University Rotterdam, Erasmus School of Health Policy & Management (ESHPM) Bügel, Jean-Bart; Franciscus Gasthuis en Vlietland, Finance and Control Birnie, Erwin; Franciscus Gasthuis en Vlietland, Franciscus Academy; Universitair Medisch Centrum Groningen, Department of Genetics
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QCI-Framework: Evaluating healthcare costs and health outcomes on an institutional level, based on Value Based Healthcare principles

A retrospective cohort study

Veghel W.H.P. van [1]* Msc, Dijk S.C. van MD PhD[2], Klem T.M.A.L MD PhD.[3], Weel A.E.A.M. MD PhD[4,5], Bügel JB.Msc[1], Birnie E. PhD [6,7]

1. Department of Finance and Control, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
2. Department of Geriatrics, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
3. Breast Clinic, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
4. Department of Rheumatology, Maasstad Hospital, Rotterdam the Netherlands
5. Erasmus School of Health Policy & Management (ESHPM), Erasmus University Rotterdam, Rotterdam the Netherlands
6. Franciscus Academy, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
7. Department of Genetics, UMC Groningen, University of Groningen, Groningen the Netherlands

Address for contact:
W.H.P. van Veghel MSc

Address: Vlietlandplein 2, Schiedam, the Netherlands

Zip code: 3118 JH

M: +31 612679714
E: W.veghel@franciscus.nl

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Abstract

Objectives

To develop a pragmatic framework, based on value based healthcare principles, to monitor health outcomes per unit costs on an institutional level. Subsequently we investigated the association between health outcomes and healthcare utilization costs.

Design

A retrospective cohort study

Setting

A teaching hospital in Rotterdam, The Netherlands

Participants

The study was performed in two use cases. The bariatric population contained 856 patients of which 639 were diagnosed with Morbid obesity BMI < 45 and 217 were diagnosed with Morbid obesity BMI >= 45. The breast cancer population contained 663 patients of which 455 received a lumpectomy and 208 a mastectomy.

Primary and secondary outcome measures

The quality cost indicator (QCI) was the primary measures and was defined as

QCI = (resulting outcome * 100) / average total costs (per thousand Euros).

Where average total costs entail all healthcare utilization costs with regard to the treatment of the primary diagnosis and follow-up care. Resulting outcome is the number of patients achieving textbook outcome (passing all health outcome indicators) divided by the total number of patients included in the care path.

Results

The breast cancer population had highest RO values (0.93) in 2020 Q4. The average total costs of the bariatric populations remained stable (AVG, € 8,905.57). Also QCI values of the bariatric and breast cancer populations showed similar variance. Finally, failing health outcome indicators was significantly related to higher hospital based costs of care in both populations.

Conclusions

The QCI framework is effective for monitoring changes in average total costs and relevant health outcomes on an institutional level. Health outcomes are associated with hospital based costs of care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- In this study, we developed a practical framework, applicable on an institutional level, to monitor quality of care in terms of health outcomes and healthcare costs.
- Research findings indicate a significant association between health outcomes and hospital based costs of care.
- To create a pragmatic and understandable framework a binary outcome measure was defined. On a patient physician level this can lead to an over or under estimation of value.
- PROMs were only incorporated in the Bariatric population in 2019 with an adherence of 60%.

Introduction

Medical costs have risen rapidly in recent decades, particularly in developed countries. This increase even exceeded the growth of the Gross Domestic Product (GDP) [1], implying that an increasing percentage of income has been spent on healthcare. Simultaneously, the gain in life expectancy was marginal and perceived health status remained approximately stable [2]. Also changing population demographics, such as aging [2] and an increasing prevalence of multimorbidity [3] and healthcare innovations [4] contributed to the rise in healthcare costs. Therefore an improved health-related effectiveness evaluation model is required to achieve affordable, high quality care in the future.

Cost Effectiveness Analysis (CEA) is the leading evaluation model to aid priority setting in healthcare budgeting [5] on the macro, national, level [6]. CEA quantifies differences in costs and outcomes for each new medical intervention compared to care as usual. In CEA value is usually defined as health-related effectiveness, and operationalized using the Quality Adjusted Life Years (QALYs) metric, while costs include healthcare and societal expenditure [7].

CEA is less suitable for priority setting on a meso, institutional, level [6]. In CEA, the QALY model includes patients' life span adjusted for health-related quality of life (HRQoL), which is based on patients' generic health status [7]. In daily practice however, this data is not available, nor easily obtained at the institutional level. Also data regarding social expenditure is neither present nor manageable on an institutional level. Furthermore, results in CEA can be hard to interpret for clinicians and healthcare managers. This makes it difficult to manage healthcare costs and health outcomes using the CEA framework.

In addition because CEA analysis are based on the patients lifespan, either the remaining lifespan should be estimated, or the analysis can only be performed after the patient is deceased. Combining quality of life and quantity of life in a single metric can then be challenging. Both are different units, one qualitative and the other qualitative, and so are not easily summarized in a single statistic.

In 2006 Porter and Teisberg proposed the concept of Value Based Healthcare (VBHC) [8]. VBHC describes value as patient centered health outcomes per unit costs. CEA and VBHC both agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However in CEA health outcomes are based on generic HRQoL measures whereas in VBHC relevant outcomes have been defined as disease or care path specific indicators. The latter approach makes VBHC more feasible at the institutional level [6], because care paths are well defined and disease specific clinical outcome measures are registered in the electronic medical records (EMR).

For benchmarking between institutions and measuring outcomes within an institution over time, health outcomes need to be standardized [10]. The International Consortium for Health Outcomes Measurement (ICHOM) has therefore published several sets of "patient-centered outcome measures" [11,12,13,14].

Because health outcomes are anyhow disease specific, they are inherently multidimensional and can vary between patients and over time. Several VBHC studies applied or proposed a multi-criteria analysis to summarize multiple outcome indicators into one metric [9,15,16, 17]. Yet, there is no standardized operational VBHC 'common metric system' that aggregates care path specific outcomes over time. Also for most indicators there is no clear criterion when such a relevant outcome is either fully achieved, failed or partially achieved. However if a single VBHC metric produces understandable results, it could support managerial decision making on an institutional level.

Because current frameworks have a high complexity and limited applicability for priority setting on an institutional [6] level, we propose a more pragmatic framework that includes costs and outcomes of care paths over time. Such a framework can be used for monitoring care paths, identification of suboptimalities within care paths, and serve as reference for quality improvement programs and quality improvement reports at the institutional level. Furthermore, we will investigate if the framework can be utilized for clinical and managerial decision making and/or quality of care assessments in daily clinical practice. Finally, we will analyze which (combination of) health outcomes are associated with increases in healthcare costs.

Methods

Patient population

This proof of concept study was a retrospective, real world cohort study, performed in two use cases, namely: bariatric surgery and breast cancer surgery in Franciscus Gasthuis & Vlietland Hospital, a large medical teaching hospital in Rotterdam, The Netherlands.

Bariatric population

For the bariatric population, all aged >= 18 year older patients diagnosed with morbid obesity (BMI >= 40) , treated with gastric bypass or a gastric sleeve resection surgery in 2019 or 2020 were included. Patient who received bariatric surgery in previous years were excluded because it was unclear if/ when a new primary treatment started and the previous treatment stopped.

Breast cancer population

For the breast cancer population, all patients aged >= 18 year older diagnosed with malignant mammary neoplasm and treated with a mastectomy, wide local excision, and possibly a breast reconstruction in 2019 or 2020 were included. Patients with stage IV breast cancer at the start of the care path were excluded, because they received palliative care. Also patients with any breast cancer diagnosis prior to the study were excluded because it was unclear if/ when the new primary treatment started and the previous treatment stopped.

Quality Cost Indicator Model

In collaboration with physicians, patient representatives and healthcare managers we developed a model to support managerial decision making based on VBHC principles: the quality cost indicator (QCI) model. This model was built on five concepts: textbook outcome resulting outcome, average total costs, QCI date and QCI period. Each of these concepts are described below.

Textbook Outcome*:* Textbook outcome (TO) [18] is accomplished when patients meet all health outcome indicators, as defined for a specific care path. For example, survival should and HRQoL can be a part of TO.

Resulting outcome*:* The resulting outcome (RO) rate refers to the number of patients who achieved TO divided by the total number of patients included in the care path. RO varies between 0 and 1.

Average total costs: Total costs are calculated as the sum of the healthcare utilization costs incurred at the healthcare provider. These costs include, the costs of the primary treatment plus any costs following the treatment of symptoms, adverse events (AEs) or comorbidities of the evaluated patients. The average total costs equals the total costs divided by the total number of patients included in the care path.

QCI date: The TO, RO and average total costs parameters are attributed to a QCI date. This is a specific date for each patient, such as the surgery date or date of diagnosis depending on the intervention that will be evaluated.

QCI period: The QCI period is a follow-up period in which the outcomes (TO and RO) and costs should be determined. All costs, RO and TO should be considered from the start of the care path (which can occur before the QCI date) until the end of the QCI period. The length of the QCI period can vary according to the goal of the analysis. For example, short term cost analysis and managerial decisions often require a short QCI period while treatment effectiveness from a the patients' and/ or physicians' perspective can require a longer QCI period.

With these five concepts in mind, QCI values can be calculated as follows:

QCI = (resulting outcome * 100) / average total costs (per thousand Euros)

Outcome indicators

The following outcome indicators were defined to calculate RO over time.

Bariatric outcomes

Because there is no VBHC standard outcome indicator set for bariatric surgery, outcome indicators were defined by physicians in consultation with patient representatives. This was achieved via flowtables in which patients provided feedback to physicians on what they found high quality care. Table 1 summarizes the outcome indicators for the bariatric population (Appendix 1 shows the full definitions) .

QCI values for the bariatric population were calculated twice, once including and once excluding the HRQoL indicator. QCI values including HRQoL were only calculated for surgery dates in 2019 due to data availability.

Breast cancer outcomes

Table 1 also shows the clinical outcome indicators for the breast cancer population, which were based on the ICHOM set [11] (again appendix 1 shows the full definitions). Because PROMs have only been incorporated in breast cancer care since 2021, we were unable to include the HRQoL indicator.

Patient population	Clinical outcome indicator	Threshold value
Bariatric	Re-operation	If a surgery related to the bariatric treatment was performed within 30 days following the primary surgery the treatment failed to meet the clinical outcome indicator.
	Deficiency	The mineral and vitamin blood level measure after 9 month and before 21 months (local protocol) closest to one year mark post-surgery was used as the measure to decide if the patient was deficient. If in this measure any of the blood levels were below the norm level the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	If there was an additional unplanned admission related to the primary diagnosis (not as a result of an additional surgery) the treatment failed to meet the clinical outcome indicator.
	Admission time	If admission time of the admission related to the primary surgery exceeded 72 hours the treatment failed to meet the clinical outcome indicator.
	Emergency Department visit (ED)	If there was an ED visit related to the bariatric treatment within 30 days post-surgery the treatment failed to meet the clinical outcome indicator.
	Total weight loss (TWL)	If TWL exceeded 20% within 455 days (local protocol) following the surgery the clinical outcome indicator was considered successfully passed.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.
	HRQoL	HRQoL was measured for the bariatric population using the RAND-36 scale of physical health [20]. When the physical health scale one year post-surgery was improved or a least equal to the physical health scale pre-surgery, the HRQoL indicator was considered to be successfully passed.
Breast Cancer	Re-operation	If a patient received a surgery due to an infections or bleeding as the result of the primary surgery the treatment failed to meet the clinical outcome indicator.
	Surgical Margins	If a patient received a re-lumpectomy due to positive surgical margins the treatment failed to meet the clinical outcome indicator.
	Recurrence	If a patient received a lumpectomy or mastectomy to treat a recurrence the treatment failed to meet the clinical outcome indicator.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.

Table 1. Description of the clinical outcome indicators per population.

Health care Utilization Costs

For each patient, total costs were calculated as number of activities of care * costs per unit of each activity. For example, the number of MRI scans * costs per MRI scan. Activities of care are specified according to the nationwide Dutch cost price model [20] which covers all hospital-based costs (not reimbursement fees). The Dutch cost price model relates cost per units of specific activities to the diagnosis for which the activity is performed. At one point in time, one activity can be used to treat one diagnosis. Therefore the primary and follow-up diagnosis needed to be included for all populations.

Bariatric utilization costs

For the bariatric population, all healthcare utilization costs based on a morbid obesity diagnosis in the surgery department and on an adiposity/obesity diagnosis in the internal medicine department were included. Moreover, costs related to readmissions or ED visits within the bariatric population were included when one of the diagnoses in Appendix 1 was present.

Breast cancer utilization costs

For the breast cancer population all healthcare utilization costs based on a malignant mammary neoplasm diagnosis in the surgery department and based on a mammary malignancy diagnosis in the internal medicine department were used.

Reference prices from 2019 were used to calculate costs for both populations throughout the entire QCI period. Finally, for calculating additional costs of expensive medication, average billing prices per medication were calculated and multiplied by the number of times these were administered per patient. These costs were then added to the utilization costs of the patient to complete the full hospital based costs of care.

QCI date and period

For all populations, the QCI date was selected as the surgery date. The QCI follow-up period was set at 1 year. To include all costs of the treatment for all patients, all costs from one year prior to the QCI date (2019 or 2020) until the end of the QCI period (2020 or 2021) were included.

Outcome categorization

For analyzing the association between outcome indicators and costs, outcome indicators need to contain a minimum number of patients per outcome status (achieved / failed). Because some indicators were failed only a few times, indicators were categorized. The categories were defined such that they contained at least 5 patients.

Bariatric outcome categories

The bariatric population contained the following outcome indicator categories:

- Admission time after the primary surgery failed
- Deficiency failed
- ED visit failed
- TWL failed
- Other failed
- Textbook outcome

Each category except Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). The Other failed category contained patients who either failed the re-operation or re-admission indicator or a combination of indicators.

Due to differences in outcomes (achieved / failed outcome indicators) between the bariatric population including and excluding HRQoL, the admission time failed category was replaced by the HRQoL failed category, containing patients who only failed the HRQoL indicator, in the population including HRQoL. The Other failed

category therefore contained patients who either failed the re-operation, admission time or re-admission indicator or a combination of indicators. All other outcome categories remained the same.

Breast outcome categories

For the breast cancer population, the outcome categories were as follows:

- Positive Margins failed
- Reoperation failed
- Other failed
- Textbook outcome

Again all categories except the Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). Patients in the Other failed category either failed the recurrence or survival indicators or failed multiple indicators.

Analysis

Stratification

To increase comparability of QCI values and average costs we adjusted costs and RO values for patient characteristics using stratification.

Bariatric population

The bariatric population was stratified according to:

- Gender
- Age (</>=50 years)
- Body Mass Index (BMI) at the start of the treatment (BMI ≥45, or BMI<45).

National guidelines indicated that gender, BMI and age impact the costs and outcomes of the treatment [21]. Data of the bariatric population also showed that patients over 50 had relatively higher costs than patients under 50.

Breast cancer population

The breast cancer population was stratified for:

- Age (</>=70 years)
- Tumor, nodule, metastasis score (TNM) / ductal carcinoma in situ (DCIS)
- Estrogen receptor (ER) status
- Human epidermal growth factor receptor 2 (HER2) status.

As per national guidelines these patient and disease specific characteristics indicate whether new (expensive) medication will be administered. These characteristics therefore have a large effect on costs of care[22].

Case mix adjusted values

Expected RO and costs values per quarter were calculated as the sum of the average RO and costs of the total study period per stratum (group) multiplied by the percentage of the different stratums of the population in that quarter [23]. Adjusted RO and average total costs (per quarter) were then calculated as follows:

Adjusted RO = average observed RO * (observed RO / expected RO)

Adjusted Average Total Costs = average observed Average Total Costs * (observed Total Costs / expected Average Total Costs)

Missing data

Missing indicator data could indicate an increased likelihood of failing or succeeding the indicator. With this in mind, we couldn't estimate TO for patients with missing indicator data. Therefore all patients missing one or more clinical indicators were excluded from all analysis.

Statistical Testing

The Kruskal-Wallis test with an alpha value of 0.05 (two-sided) was used to determine whether costs were significantly different across outcome categories within populations.

Results

Patient population

Bariatric population

In total, 1172 patients had bariatric surgery between 2019-2020. Due to missing clinical data, 316 patients (27%) were excluded. Of the 856 remaining patients, 639 had a BMI lower than 45 at the start of the treatment (Table 2). Regarding the Bariatric HRQoL population, 270 patients were included of which 203 were diagnosed with a BMI lower than 45 at the start of the treatment.

Breast cancer population

In 2019-2020, a total of 671 patients underwent breast cancer surgery. Eight patients had cancer stage IV at the start of the treatment and were excluded. Of the remaining 663 patients, 208 received a mastectomy and 455 received a lumpectomy.

Bariatric (n=856)*			
Age, median (interquartile range)		46y (34 - 53)y	
Diagnosis	Morbid obesity BMI < 45	639	75%
	Morbid obesity BMI >= 45	217	25%
Gender	M	177	21%
	F	679	79%
Surgery type	Bypass	422	49%
	Sleeve	434	51%
Bariatric including HRQoL (n=270)			
Age, median (interquartile range)		46y (34y -52,75y)	
BMI	Morbid obesity BMI < 45	203	75%
	Morbid obesity BMI >= 45	67	25%
Gender	M	57	21%
	F	213	79%
Surgery type	Bypass	136	50%
	Sleeve	134	50%
Breast Cancer (n=663)			
Age, median (interquartile range)		63y (52y – 72y)	
Cancer stage	0	102	15%
	I	280	42%
	II	236	36%
	III	45	7%
Estrogen receptor (ER) status	Pos	406	61%
	Neg	87	13%
	Unknown	170	26%
human epidermal growth factor receptor 2 (HER2) status	Pos	56	8%
	Neg	437	66%
	Unknown	170	26%
Surgery type	Mastectomy	208	31%
	Lumpectomy	455	69%
neoadjuvant chemotherapy	Yes	122	18%
	No	541	82%
adjuvant chemotherapy	Yes	148	22%
	No	515	78%

Table 2: Characteristics of the breast cancer population and bariatric population with and without HRQoL (number of patients en percentages of total)

**No overt differences in case mix characteristics between the bariatric population in and excluding missing data.*

Outcome indicators over time

Table 3 describes the crude percentages of patients achieving the health outcome indicator and resulting outcome per year quarter and in total within the different populations.

Population	Outcome indicator	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Total
Baratric care (n=856)	Re-operation	105/2	129/2	90/2	130/3	85/4	54/0	171/2	77/0	**841/15**
		98%	98%	98%	98%	96%	100%	99%	100%	***98%***
	Deficiency	83/24	96/34	64/28	89/44	59/30	39/15	127/45	61/16	**618/236**
		78%	74%	70%	67%	66%	72%	74%	79%	**72%**
	Re-admission	105/2	129/2	90/2	128/5	88/1	54/0	167/6	76/1	**837/19**
		98%	98%	98%	96%	99%	100%	97%	99%	**98%**
	Admission time	102/5	125/6	87/5	130/3	86/3	52/2	162/11	74/3	**818/38**
		95%	95%	95%	98%	97%	96%	94%	96%	**96%**
	ER visit	101/6	121/10	88/4	122/11	81/8	52/2	160/13	74/3	**799/57**
		94%	92%	96%	92%	91%	96%	92%	96%	**93%**
	TWL (total weight loss)	104/3	123/8	80/12	122/11	84/5	52/2	165/7	77/0	**807/48**
		97%	94%	87%	92%	94%	96%	96%	100%	**94%**
	Survival	107/0	130/1	92/0	133/0	89/0	54/0	172/1	77/0	**854/2**
		100%	99%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**72/35**	**81/50**	**47/45**	**73/60**	**50/39**	**34/20**	**107/66**	**56/21**	**520/336**
		67%	**62%**	**51%**	**55%**	**56%**	**63%**	**62%**	**73%**	**61%**
Bariatric including HRQoL care (n=270)	Re-operation	41/2	82/0	56/1	86/2	- /-	- /-	- /-	- /-	**265/5**
		95%	100%	98%	98%	-	-	-	-	**98%**
	Deficiency	32/11	64/18	41/16	60/28	- /-	- /-	- /-	- /-	**197/73**
		74%	78%	72%	68%	-	-	-	-	**73%**
	Re-admission	42/1	82/0	55/2	86/2	- /-	- /-	- /-	- /-	**265/5**
		98%	100%	96%	93%	-	-	-	-	**98%**
	Admission time	40/3	81/1	56/1	86/2	- /-	- /-	- /-	- /-	**263/7**
		93%	99%	98%	98%	-	-	-	-	**97%**
	ER visit	42/1	76/6	53/4	82/6	- /-	- /-	- /-	- /-	**253/17**
		98%	93%	93%	93%	-	-	-	-	**94%**
	TWL (total weight loss)	43/0	80/2	52/5	80/8	- /-	- /-	- /-	- /-	**255/15**
		100%	98%	91%	91%	-	-	-	-	**94%**
	HRQoL	42/1	80/2	53/4	82/6	- /-	- /-	- /-	- /-	**257/13**
		98%	98%	93%	93%	-	-	-	-	**95%**
	Survival	43/0	82/0	57/0	88/0	- /-	- /-	- /-	- /-	**270/0**

		100%	100%	100%	100%	-	-	-	-	**100%**
	Resulting outcome * 100%	**29/14**	**56/26**	**31/26**	**48/40**	**- /-**	**- /-**	**- /-**	**- /-**	**164/106**
		67%	**68%**	**54%**	**55%**	**-**	**-**	**-**	**-**	**61%**
Breast cancer care (n=663)	Re-operation	79/3	55/6	77/3	75/6	88/7	86/5	85/3	83/2	**628/35**
		96%	90%	96%	93%	93%	95%	97%	98%	**95%**
	Survival	82/0	60/1	80/0	81/0	94/1	90/1	87/1	85/0	**659/4**
		100%	98%	100%	100%	99%	99%	99%	100%	**99%**
	Surgical margins	75/7	57/4	74/6	74/7	85/10	87/4	76/12	81/4	**609/54**
		91%	93%	93%	91%	89%	96%	86%	95%	**92%**
	Recurrance	82/0	61/0	80/0	81/0	95/0	91/0	87/1	85/0	**662/1**
		100%	100%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**73/9**	**51/10**	**72/8**	**70/11**	**78/17**	**81/10**	**72/16**	**79/6**	**576/87**
		89%	**84%**	**90%**	**86%**	**82%**	**89%**	**82%**	**93%**	**87%**

Table 3: Number (successful / not successful) and percentage of patients achieving the respective Health outcome indicator per year, quarter within the different populations.

Bariatric outcomes

In the bariatric, all clinical indicators scored above 90% except the deficiency indicator, which scored 73%. Final RO was 0.61, (range 0.51- 0.73). For the Bariatric population including HRQoL RO was 0.61, range(0.54 – 0.68). During the same period, RO was 0.59 in the bariatric population excluding HRQoL. The higher RO values in the Bariatric population including HRQoL were mainly based on a higher percentage of patients achieving the TWL and deficiency indicators.

Breast cancer outcomes

In the breast cancer population RO was 0.87, range (0.82 - 0.93). The surgical margins indicator was least successful, with 92% of patients achieving it. The recurrence indicator was the most successful. It was failed by one patient in 2020 Q3.

QCI values

[Insert figure 1 here]

Figure 1. Case mix adjusted Resulting outcome (panel 1A, 1B), Average total costs (panel 2A, 2B) and QCI values (panel 3A, 3B) over time for both populations.

Figure 1 displays case-mix adjusted RO (panel 1A, 1B), Average total costs (panel 2A, 2B) and resulting QCI values (3A and 3B).

Bariatric RO, Cost and QCI values

For the bariatric population RO, Average total cost and QCI values are presented twice, once including the HRQoL indicator and once for the total bariatric population. As presented in panel 1A, RO values of the Bariatric population including HRQoL are higher compared to the total Bariatric population. Because average total costs of both groups are similar (Panel 2A), QCI values of the Bariatric population including HRQoL are higher in 2019 Q2 and Q3. Overall, because average total costs of the bariatric population has a low variance (SD = €449,85) deviations in QCI values are mostly due to changes in RO values.

Breast cancer RO, Cost and QCI values

The results of the breast cancer population show that QCI (panel 3B) values can be impacted by a combination of both costs (panel 2B) and RO (panel 1B). For the breast cancer population this is especially true in 2019 Q3 and 2020 Q1. In 2019 Q3 QCI values were highest due to a combination of low costs and high RO values. The opposite is true for 2020 Q1 were a combination of high costs and low RO values resulted in the lowest QCI value.

Costs per population per outcome Category

Table 4 describes the characteristics of the cost distributions per outcome category for each population.

Population	Outcome category	Number of patients	Average Costs	Standard Deviation Costs	Interquartile Range (IQR) of Costs	P Value
Bariatric care	Admission time failed	21	€ 11,854.96	€ 4,535.65	€ 3,465.92	< 0.01
	Deficiency failed	192	€ 8,452.58	€ 1,457.45	€ 1,603.95	
	ER visit failed	25	€ 8,867.37	€ 1,778.55	€ 1,697.46	
	Other failed	66	€ 12,871.99	€ 10,290.17	€ 3,915.20	
	Textbook outcome	520	€ 8,470.70	€ 1,450.37	€ 1,599.11	
	TWL failed	32	€ 8,603.64	€ 1,448.56	€ 1,685.98	
Bariatric care including HRQoL	HRQoL Failed	6	€ 9,267.24	€ 3,587.81	€ 1,754.82	< 0.01
	Deficiency failed	54	€ 8,404.37	€ 1,173.08	€ 1,236.08	
	ER visit failed	7	€ 8,661.00	€ 888.35	€ 1,192.50	
	Other failed	30	€ 12,189.78	€ 1,0887.56	€ 2,235.78	
	Textbook outcome	164	€ 8,483.20	€ 1,263.51	€ 1,536.37	
	TWL failed	9	€ 8,165.08	€ 1,029.86	€ 1,733.97	
Breast cancer care	Other failed	11	€ 18,231.83	€ 8,878.90	€ 12,516.42	< 0.01
	Positive Margins failed	47	€ 14,772.80	€ 10,234.77	€ 7,093.75	
	Reoperation failed	29	€ 18,792.08	€ 12,317.22	€ 10,084.12	
	Textbook outcome	576	€ 12,277.29	€ 10,273.12	€ 6,666.06	

Table 4: Descriptive measures of the total costs per outcome category for each population. P values refer to the overall difference in total costs across outcome categories within populations.

Costs of care per outcome category for the bariatric population

For the bariatric population, patients in the Other failed and Admission time failed categories had high average costs of care, compared to the other categories. The Other failed category also had the highest standard deviation and IQR. For the bariatric population including HRQoL, patients in the Other failed category had the highest average costs of care whereas patients in the TWL failed category had the lowest average costs. Total costs by outcome category differed significantly for both populations.

Costs of care per outcome category for breast cancer population

For breast cancer patients, the average costs of the Reoperation failed and Other failed outcome categories were comparable. Patients in the Textbook outcome category had the lowest average costs of care. Again total costs by outcome category differed significantly.

Discussion

In this proof of concept study, we developed the QCI model in collaboration with physicians, patient representatives and healthcare managers based on VBHC principles. The QCI model suits the need for monitoring healthcare costs and health outcomes, and thereby the evaluation and quality assessment of healthcare interventions or quality improvements on an institutional level. The framework provides management information on (patient perceived) health outcomes and costs in a single metric and underlying components, for clinicians and healthcare management.

The results show that the QCI framework is sensitive to changes in average total costs and RO. A strength of the QCI framework is that routinely collected cost and outcome data from EMR and PROMS software are directly available for QCI analysis. Furthermore, the QCI framework has a high level of flexibility because health gains can be based on a large variety of outcomes, preferably those outcomes that cover all main health effects associated with the care path. This flexibility in outcomes also makes the QCI framework applicable for a variety of medical conditions. These findings indicate that the framework is suitable for monitoring performance of care in terms of outcomes and costs in clinical practice, on an institutional level. Using the framework in a plan do act check (PDCA) cycle, with or without using the underlying indicator and cost data, should help evaluate results and guide continued improvement processes [24].

Not all outcome categories equally affected hospital based costs of care. Failure of outcome indicators with regard to surgery were associated with higher costs. These results can be explained by the direct impact of surgical procedures on hospital based costs [25]. However no direct impact of the deficiency and TWL indicators on hospital based costs of care was visible. On the other hand, deficiencies can lead to the development of metabolic bone diseases in the long-term [26] and obesity is a known risk for coronary heart disease [27]. The follow-up period of one year might not have been sufficient to investigate the expected increase in cost due to these complications. Investing in adherence to follow up could result in a higher percentage of patients passing the TWL and deficiency indicators thereby possibly preventing these long-term costs [28]. Investing in adherence to follow up could therefore, in short term QCI analysis, lead to higher costs and a higher RO. This indicates that short term QCI values can either improve or decrease depending on whether the gain in RO outweighs the gain in costs. In a long term QCI analysis, QCI values could improve as additional costs to treat the aforementioned complications could be avoided and RO increases. Different follow-up periods could therefore result in different QCI values.

VBHC, CEA and QCI all agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However both VBHC and CEA require complex calculations to summarize outcomes [7, 9,15,16, 17]. In contrast, in QCI the RO parameter is an understandable statistic summarizing outcomes. Also, in the basis, VBHC and CEA include social as well as direct healthcare costs. QCI, in this analysis, is limited to costs incurred at the healthcare provider. This matches the clinician and managerial perspective. Alternatively, the model could also include out-of-hospital costs and non-medical costs if this is relevant for hospital management. Finally, both CEA and VBHC recommend analysis of the full cycle of care. In QCI different follow-up period are available, because short-run or medium term analysis can provide valuable information for managerial purposes.

The definition of TO as “all clinical outcome indicators are met” gives healthcare providers a pragmatic method to summarize outcomes. However a limitation of this binary scoring model is that value is only created when all health indicators are met (1), and no value is created when at least one of the indicators is failed (0). In the first case, when all indicators are passed, the patient can still perceive the treatment as less then optimal. In the latter case, the patient can view the treatment (at least partially) as a success. The binary scoring rule could therefore result in an overestimation of value, but is more likely to lead to an underestimation of value. An alternative approach could be to define an outcome measure with a continuous score that varies between completely suboptimal outcome (0) and completely optimal outcome (100), with or without assigning different weights to different outcome indicators. Another limitation is missing data. When data from one indicator is missing and the other indicators are passed, QCI values are not defined. Because the QCI framework can give an under- as well over-estimation (or no estimation in the case of missing data) of value on the micro level(physician-patient encounter) [6], the framework isn’t applicable at this level. The QCI model can give

valuable information on an institutional level as it summarizes group outcomes and costs in an understandable fashion.

Areas of future research include defining upper and lower margins for outcome, costs and QCI values to guide continued improvement processes. Because as time passes chances of failing or succeeding an indicator can vary [29], future research should investigate RO and TO values over multiple follow-up periods. Comparing hospital performance using the QCI framework could be helpful for optimizing QCI values and underlying costs and outcome results [30]. Finally, the QCI framework should be applied to more medical conditions, in chronic and acute settings to study the generalizability of the properties of the QCI model.

Conclusions

This proof of concept study showed that the QCI framework is effective for monitoring the performance of care paths in terms of costs and health outcomes on an institutional level. An overall impact of health outcome indicators on hospital based costs of care is found. Also, some indicators, or combination of indicators, impact costs more than others.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval statements that refer to your institution

Because the study evaluated care as usual a METC review isn't obliged under Dutch Legislation. The Institutional Review Board of the Franciscus Gasthuis & Vlietland hospital, named Advies Commissie Wetenschap (ACW) reviewed and waived the study protocol (ref. 2023-002). The study was conducted in accordance with the Declaration of Helsinki.

Contributorship statement

The study was conceived by WHP and JB. Data collection, analysis were performed by WHP. The manuscript was drafted by WHP and EB. Methodological and statistical integrity was checked by EB. SB, TMALK, and AEAMvW provided feedback on the manuscript. All authors read and approved the final manuscript.

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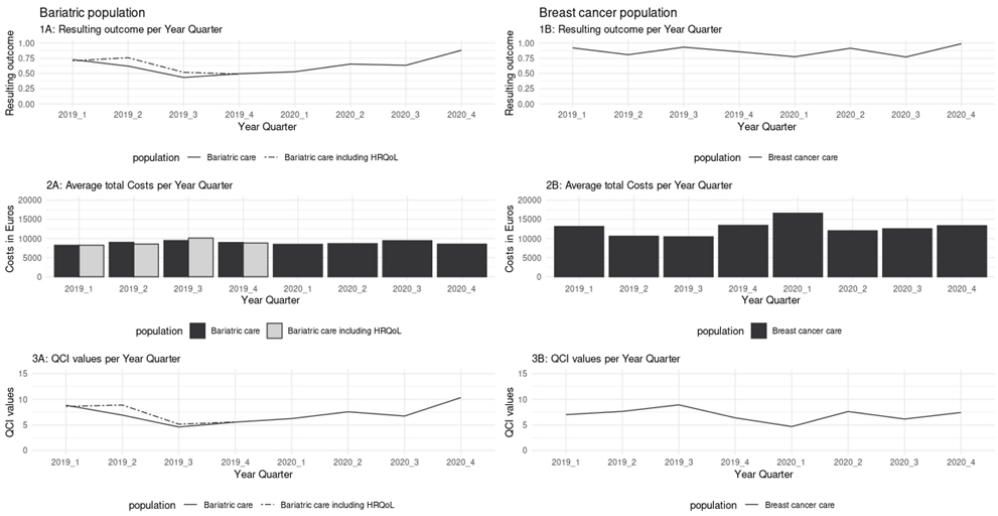
Availability of data and materials

The datasets used in this study are not publicly available under the Dutch privacy legislation. Anonymized datasets can be made available from the corresponding author on reasonable request



663x345mm (38 x 38 DPI)

Appendix 1: Health outcome indicators

Patient population	KPI	Description	Success measure
Bariatric	Re-operation	The following surgeries within 30 days of the primary surgery were taken into account: - Operative treatment for esophageal perforation - Endoscopic extension gastric bypass - Endoscopic sleeve and Pouch bypass - Endoscopic gastronomy - Overstitching stomach perforation (open/ endoscopic) - Endoscopic small intestine resection - Endoscopic intestinal anastomosis - Overstitching intestinal perforation (open / laparoscopic) - Cholecystectomy laparoscopic - Laparotomy - Closure of the Petersen mesenteric defect - Bleeding within 24 hours of the primary surgery - Incisional hernia (open / laparoscopic)	If a surgery was performed within 30 days following the primary surgery, the treatment failed to meet the clinical outcome indicator.
	Deficiency	The following blood levels were measured: - Ferritine (22 µg/L) - Active B12 (32 pmol/L) - Folate (7 nmol/L) - Vitamin B1 (70 nmol/L) - Vitamin B6 (35 nmol/L) - Vitamin D (50 nmol/L)	The blood level measure after 9 months and before 21 months closed to one year mark post-surgery was used as the measure to decide if the patient had deficiencies. If in this measure any of the blood levels were below the norm levels the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	Hospital admissions within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation	If there was an additional unplanned admission the treatment was stated to have failed to meet the clinical outcome indicator.

		- Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	
	Admission time	Admission time directly following the surgery	If admission time of the primary admission exceeded 72 hours treatment was stated to have failed to meet the clinical outcome indicator.
	ED	Emergency deparment visits within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation - Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	If there was an emergency department visit within 30 post surgery the treatment failed to meet the clinical outcome indicator.
	TWL (total weight loss)	(Initial weight – current weight) / initial weight	If TWL exceeded 20% in a period of 455 days following the surgery the clinical outcome indicator was considered successfully passed.

Breast Cancer	Re-operation	All surgeries due to infections or bleeding as a result of the primary surgery:	Once a patient received a surgery due to infections or bleeding the treatment was stated to have failed to meet the clinical outcome indicator.
	Surgical Margins	All patients who received surgery (lumpectomy or mastectomy) due to close or positive margins	Once a patient did receive surgery the treatment the treatment was stated to have failed to meet the clinical outcome indicator. If margins did not need a further surgery the clinical outcome indicator was considered to be successfully passed.
	Recurrence	All who had a recurrence of the primary tumor. It was considered all these patients did receive surgery (either an mastectomy or mastectomy).	Once the patient received surgery to treat the recurrence the treatment the treatment was stated to have failed to meet the clinical outcome indicator.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title page
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4&6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4&5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5&6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6&7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	10 up to 13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	13
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Is the QCI framework suited for monitoring outcomes and costs in a teaching hospital using Value Based Healthcare principles?: A retrospective cohort study

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Is the QCI framework suited for monitoring outcomes and costs in a teaching hospital using Value Based Healthcare principles?: A retrospective cohort study

Veghel W.H.P. van [1]* Msc, Dijk S.C. van MD PhD[2], Klem T.M.A.L MD PhD.[3], Weel A.E.A.M. MD PhD[4,5], Bügel JB.Msc[1], Birnie E. PhD [6,7]

1. Department of Finance and Control, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
2. Department of Geriatrics, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
3. Breast Clinic, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
4. Department of Rheumatology, Maasstad Hospital, Rotterdam the Netherlands
5. Erasmus School of Health Policy & Management (ESHPM), Erasmus University Rotterdam, Rotterdam the Netherlands
6. Franciscus Academy, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
7. Department of Genetics, UMC Groningen, University of Groningen, Groningen the Netherlands

Address for contact:
W.H.P. van Veghel MSc

Address: Vlietlandplein 2, Schiedam, the Netherlands

Zip code: 3118 JH

M: +31 612679714
E: W.veghel@franciscus.nl

Keywords

Value Based Healthcare, Health outcomes, Healthcare costs, Evaluation of care, Care pathways

Word count

4032

Abstract

Objectives

To develop a pragmatic framework, based on value based healthcare principles, to monitor health outcomes per unit costs on an institutional level. Subsequently we investigated the association between health outcomes and healthcare utilization costs.

Design

A retrospective cohort study

Setting

A teaching hospital in Rotterdam, The Netherlands

Participants

The study was performed in two use cases. The bariatric population contained 856 patients of which 639 were diagnosed with Morbid obesity BMI < 45 and 217 were diagnosed with Morbid obesity BMI >= 45. The breast cancer population contained 663 patients of which 455 received a lumpectomy and 208 a mastectomy.

Primary and secondary outcome measures

The quality cost indicator (QCI) was the primary measures and was defined as

QCI = (resulting outcome * 100) / average total costs (per thousand Euros).

Where average total costs entail all healthcare utilization costs with regard to the treatment of the primary diagnosis and follow-up care. Resulting outcome is the number of patients achieving textbook outcome (passing all health outcome indicators) divided by the total number of patients included in the care path.

Results

The breast cancer and bariatric population had highest resulting outcome values in 2020 Q4, 0.92 and 0.74 respectively. The average total costs of the bariatric population remained stable (avg, € 8,833.55, min € 8,494.32, max € 9,164.26). The breast cancer population showed higher variance in costs (avg, € 12,735.31 min € 12,188.83, max € 13,695.58). QCI values of both populations showed similar variance (0.3 and 0.8). Failing health outcome indicators was significantly related to higher hospital based costs of care in both populations ($P < 0.01$).

Conclusions

The QCI framework is effective for monitoring changes in average total costs and relevant health outcomes on an institutional level. Health outcomes are associated with hospital based costs of care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study included multiple populations with a large number of patients followed over a prolonged period.
- In the study multiple clinical indicators and patient reported outcomes were defined to calculate Textbook and resulted outcome.
- To create a pragmatic framework a binary outcome measure was defined. On a patient-physician level this can lead to an over- or under estimation of value.

Introduction

Medical costs have risen rapidly in recent decades, particularly in developed countries. This increase even exceeded the growth of the Gross Domestic Product (GDP) [1], implying that an increasing percentage of GDP has been spent on healthcare. Simultaneously, the gain in life expectancy was marginal and perceived health status remained approximately stable [2]. Also changing population demographics, such as aging [2] and an increasing prevalence of multimorbidity [3] and healthcare innovations [4] contributed to the rise in healthcare costs. Therefore an improved health-related effectiveness evaluation model is required to achieve affordable, high quality care in the future.

Cost Effectiveness Analysis (CEA) is the leading evaluation model to aid priority setting in healthcare budgeting [5] on the macro, national, level [6]. CEA quantifies differences in costs and outcomes for each new medical intervention compared to care as usual. In CEA value is usually defined as health-related effectiveness, and operationalized using the Quality Adjusted Life Years (QALYs) metric, while costs include healthcare and societal expenditure [7].

CEA is less suitable for priority setting on a meso, institutional, level [6]. In CEA, the QALY model includes patients' life span adjusted for health-related quality of life (HRQoL), which is based on patients' generic health status [7]. In daily practice however, this data is not available, nor easily obtained at the institutional level. Also data regarding social expenditure is neither present nor manageable on an institutional level. Furthermore, results in CEA can be hard to interpret for clinicians and healthcare managers. This makes it difficult to manage healthcare costs and health outcomes using the CEA framework.

In addition because CEA analysis are based on the patients lifespan, either the remaining lifespan should be estimated, or the analysis can only be performed after the patient is deceased. Combining quality of life and quantity of life in a single metric can then be challenging. Both are different units, one qualitative and the other qualitative, and so are not easily summarized in a single statistic.

In 2006 Porter and Teisberg proposed the concept of Value Based Healthcare (VBHC) [8]. VBHC describes value as patient centered health outcomes per unit costs. CEA and VBHC both agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However in CEA health outcomes are based on generic HRQoL measures whereas in VBHC relevant outcomes have been defined as disease or care path specific indicators. The latter approach makes VBHC more feasible at the institutional level [6], because care paths are well defined and disease specific clinical outcome measures are registered in the electronic medical records (EMR).

For benchmarking between institutions and measuring outcomes within an institution over time, health outcomes need to be standardized [10]. The International Consortium for Health Outcomes Measurement (ICHOM) has therefore published several sets of "patient-centered outcome measures" [11,12,13,14].

Because health outcomes are anyhow disease specific, they are inherently multidimensional and can vary between patients and over time. Several VBHC studies applied or proposed a multi-criteria analysis to summarize multiple outcome indicators into one metric [9,15,16, 17]. Yet, there is no standardized operational VBHC 'common metric system' that aggregates care path specific outcomes over time. Also for most indicators there is no clear criterion when such a relevant outcome is either fully achieved, failed or partially achieved. However if a single VBHC metric produces understandable results, it could support managerial decision making on an institutional level.

Because current frameworks have a high complexity and limited applicability for priority setting on an institutional [6] level, we propose a more pragmatic framework that includes costs and outcomes of care paths over time. Such a framework can be used for monitoring care paths, identification of suboptimalities within care paths, and serve as reference for quality improvement programs and quality improvement reports at the institutional level. Furthermore, we will investigate if the framework can be utilized for clinical and managerial decision making and/or quality of care assessments in daily clinical practice. Finally, we will analyze which (combination of) health outcomes are associated with increases in healthcare costs.

Methods

Patient population

This proof of concept study was a retrospective, real world cohort study, performed in two use cases, namely: bariatric surgery and breast cancer surgery in Franciscus Gasthuis & Vlietland Hospital, a large medical teaching hospital in Rotterdam, The Netherlands.

Bariatric population

For the bariatric population, all aged >= 18 year older patients diagnosed with morbid obesity (Body Mass Index (BMI) >= 40) , treated with gastric bypass or a gastric sleeve resection surgery in 2019 or 2020 were included. Patient who received bariatric surgery in previous years were excluded because it was unclear if/ when a new primary treatment started and the previous treatment stopped.

Breast cancer population

For the breast cancer population, all patients aged >= 18 year older diagnosed with malignant mammary neoplasm and treated with a mastectomy, wide local excision, and possibly a breast reconstruction in 2019 or 2020 were included. Patients with stage IV breast cancer at the start of the care path were excluded, because they received palliative care. Also patients with any breast cancer diagnosis prior to the study were excluded because it was unclear if/ when the new primary treatment started and the previous treatment stopped.

Quality Cost Indicator Model

In collaboration with physicians, patient representatives and healthcare managers we developed a model to support managerial decision making based on VBHC principles: the quality cost indicator (QCI) model. This model was built on five concepts: textbook outcome (TO) resulting outcome (RO) , average total costs (ATC), QCI date and QCI period. Each of these concepts are described below.

Textbook Outcome*:* Textbook outcome (TO) [18] is accomplished when patients meet all health outcome indicators, as defined for a specific care path. For example, survival should and HRQoL can be a part of TO.

Resulting outcome*:* The resulting outcome (RO) rate refers to the number of patients who achieved TO divided by the total number of patients included in the care path. RO varies between 0 and 1.

Average total costs: Total costs (TC) are calculated as the sum of the healthcare utilization costs incurred at the healthcare provider. These costs include, the costs of the primary treatment plus any costs following the treatment of symptoms, adverse events (AEs) or comorbidities of the evaluated patients. The (ATC) equals the TC divided by the total number of patients included in the care path.

QCI date: The TO, RO and ATC parameters are attributed to a QCI date. This is a specific date for each patient, such as the surgery date or date of diagnosis depending on the intervention that will be evaluated.

QCI period: The QCI period is a follow-up period in which the outcomes (TO and RO) and costs (ATC) should be determined. All costs, RO and TO should be considered from the start of the care path (which can occur before the QCI date) until the end of the QCI period. The length of the QCI period can vary according to the goal of the analysis. For example, short term cost analysis and managerial decisions often require a short QCI period while treatment effectiveness from a the patients' and/ or physicians' perspective can require a longer QCI period.

With these five concepts in mind, QCI values can be calculated as follows:

QCI = (resulting outcome * 100) / average total costs (per thousand Euros)

Outcome indicators

The following outcome indicators were defined to calculate RO over time.

Bariatric outcomes

Because there is no VBHC standard outcome indicator set for bariatric surgery, outcome indicators were defined by physicians in consultation with patient representatives. This was achieved via flowtables in which patients provided feedback to physicians on what they found high quality care. Table 1 summarizes the outcome indicators for the bariatric population (Appendix 1 shows the full definitions) .

QCI values for the bariatric population were calculated twice, once including and once excluding the HRQoL indicator. QCI values including HRQoL were only calculated for surgery dates in 2019 due to data availability.

Breast cancer outcomes

Table 1 also shows the clinical outcome indicators for the breast cancer population, which were based on the ICHOM set [11] (again appendix 1 shows the full definitions). Because Patient Reported Outcome Measures (PROMs) have only been incorporated in breast cancer care since 2021, we were unable to include the HRQoL indicator.

Patient population	Clinical outcome indicator	Threshold value
Bariatric	Re-operation	If a surgery related to the bariatric treatment was performed within 30 days following the primary surgery the treatment failed to meet the clinical outcome indicator.
	Deficiency	The mineral and vitamin blood level measure after 9 month and before 21 months (local protocol) closest to one year mark post-surgery was used as the measure to decide if the patient was deficient. If in this measure any of the blood levels were below the norm level the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	If there was an additional unplanned admission related to the primary diagnosis (not as a result of an additional surgery) the treatment failed to meet the clinical outcome indicator.
	Admission time	If admission time of the admission related to the primary surgery exceeded 72 hours the treatment failed to meet the clinical outcome indicator.
	Emergency Department visit (ED)	If there was an ED visit related to the bariatric treatment within 30 days post-surgery the treatment failed to meet the clinical outcome indicator.
	Total weight loss (TWL)	If TWL exceeded 20% within 455 days (local protocol) following the surgery the clinical outcome indicator was considered successfully passed.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.
	HRQoL	HRQoL was measured for the bariatric population using the RAND-36 scale of physical health [19]. When the physical health scale one year post-surgery was improved or a least equal to the physical health scale pre-surgery, the HRQoL indicator was considered to be successfully passed.
Breast Cancer	Re-operation	If a patient received a surgery due to an infections or bleeding as the result of the primary surgery the treatment failed to meet the clinical outcome indicator.
	Surgical Margins	If a patient received a re-lumpectomy due to positive surgical margins the treatment failed to meet the clinical outcome indicator.
	Recurrence	If a patient received a lumpectomy or mastectomy to treat a recurrence the treatment failed to meet the clinical outcome indicator.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.

Table 1. Description of the clinical outcome indicators per population.

Health care Utilization Costs

For each patient, TC were calculated as number of activities of care * costs per unit of each activity. For example, the number of MRI scans * costs per MRI scan. Activities of care are specified according to the nationwide Dutch cost price model [20] which covers all hospital-based costs (not reimbursement fees). The Dutch cost price model relates cost per units of specific activities to the diagnosis for which the activity is performed. At one point in time, one activity can be used to treat one diagnosis. Therefore the primary and follow-up diagnosis needed to be included for all populations.

Bariatric utilization costs

For the bariatric population, all healthcare utilization costs based on a morbid obesity diagnosis in the surgery department and on an adiposity/obesity diagnosis in the internal medicine department were included. Moreover, costs related to readmissions or ED visits within the bariatric population were included when one of the diagnoses in Appendix 1 was present.

Breast cancer utilization costs

For the breast cancer population all healthcare utilization costs based on a malignant mammary neoplasm diagnosis in the surgery department and based on a mammary malignancy diagnosis in the internal medicine department were used.

Reference prices from 2019 were used to calculate costs for both populations throughout the entire QCI period. Finally, for calculating additional costs of expensive medication, average billing prices per medication were calculated and multiplied by the number of times these were administered per patient. These costs were then added to the utilization costs of the patient to complete the full hospital based costs of care.

QCI date and period

For all populations, the QCI date was selected as the surgery date. The QCI follow-up period was set at 1 year. To include all costs of the treatment for all patients, all costs from one year prior to the QCI date (2019 or 2020) until the end of the QCI period (2020 or 2021) were included.

Outcome categorization

For analyzing the association between outcome indicators and costs, outcome indicators need to contain a minimum number of patients per outcome status (achieved / failed). Because some indicators were failed only a few times, indicators were categorized. The categories were defined such that they contained at least 5 patients.

Bariatric outcome categories

The bariatric population contained the following outcome indicator categories:

- Admission time after the primary surgery failed
- Deficiency failed
- ED visit failed
- TWL failed
- Other failed
- Textbook outcome

Each category except Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). The Other failed category contained patients who either failed the re-operation or re-admission indicator or a combination of indicators.

Due to differences in outcomes (achieved / failed outcome indicators) between the bariatric population including and excluding HRQoL, the admission time failed category was replaced by the HRQoL failed category, containing patients who only failed the HRQoL indicator, in the population including HRQoL. The Other failed

category therefore contained patients who either failed the re-operation, admission time or re-admission indicator or a combination of indicators. All other outcome categories remained the same.

Breast outcome categories

For the breast cancer population, the outcome categories were as follows:

- Positive Margins failed
- Reoperation failed
- Other failed
- Textbook outcome

Again all categories except the Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). Patients in the Other failed category either failed the recurrence or survival indicators or failed multiple indicators.

Analysis

Stratification

To increase comparability of QCI values and ATC we adjusted ATC and RO values for patient characteristics using stratification.

Bariatric population

The bariatric population was stratified according to:

- Gender
- Age (</>=40 years)
- Body Mass Index (BMI) at the start of the treatment (BMI ≥45, or BMI<45).

National guidelines indicated that gender, BMI and age impact the costs and outcomes of the treatment [21]. Data of the bariatric population also showed that patients over 40 had relatively higher costs than patients under 40.

Breast cancer population

The breast cancer population was stratified for:

- Age (</>=70 years)
- Tumor, nodule, metastasis score (TNM) / ductal carcinoma in situ (DCIS)
- Estrogen receptor (ER) status
- Human epidermal growth factor receptor 2 (HER2) status.

As per national guidelines these patient and disease specific characteristics indicate whether new (expensive) medication will be administered. These characteristics therefore have a large effect on costs of care[22].

Case mix adjusted values

Expected RO and ATC values per quarter were calculated as the sum of the average RO and ATC of the total study period per stratum (group) multiplied by the percentage of the different stratums of the population in that quarter [23]. Adjusted RO and ATC (per quarter) were then calculated as follows:

Adjusted RO = average observed RO * (observed RO / expected RO)

Adjusted ATC = average observed ATC * (observed ATC / expected ATC)

Missing data

Missing indicator data could indicate an increased likelihood of failing or succeeding the indicator. With this in mind, we couldn't estimate TO for patients with missing indicator data. Therefore all patients missing one or more clinical indicators were excluded from all analysis.

Supplementary analysis

Because extreme cost outliers may influence QCI values, results were calculated with and without outliers. The cut-off value was selected at P95.

Statistical Testing

The Kruskal-Wallis test with an alpha value of 0.05 (two-sided) was used to determine whether costs were significantly different across outcome categories within populations.

Patient and public involvement

As previously mentioned, patients were involved in the development of the outcome measures via flow tables. Patients were not involved in the design or conduct of this registry based study.

Results

Patient population

Bariatric population

In total, 1172 patients had bariatric surgery between 2019-2020. Due to missing clinical data, 316 patients (27%) were excluded. Of the 856 remaining patients, 639 had a BMI lower than 45 at the start of the treatment (Table 2). Regarding the Bariatric HRQoL population, 270 patients were included of which 203 were diagnosed with a BMI lower than 45 at the start of the treatment.

Breast cancer population

In 2019-2020, a total of 671 patients underwent breast cancer surgery. Eight patients had cancer stage IV at the start of the treatment and were excluded. Of the remaining 663 patients, 208 received a mastectomy and 455 received a lumpectomy.

Bariatric (n=856)*			
Age, median (interquartile range)		46y (34 – 53)y	
Diagnosis	Morbid obesity BMI < 45	639	75%
	Morbid obesity BMI >= 45	217	25%
Gender	M	177	21%
	F	679	79%
Surgery type	Bypass	422	49%
	Sleeve	434	51%
Bariatric including HRQoL (n=270)			
Age, median (interquartile range)		46y (34y -52,75y)	
BMI	Morbid obesity BMI < 45	203	75%
	Morbid obesity BMI >= 45	67	25%
Gender	M	57	21%
	F	213	79%
Surgery type	Bypass	136	50%
	Sleeve	134	50%
Breast Cancer (n=663)			
Age, median (interquartile range)		63y (52y – 72y)	
Cancer stage	0	102	15%
	I	280	42%
	II	236	36%
	III	45	7%
Estrogen receptor (ER) status	Pos	406	61%
	Neg	87	13%
	Unknown	170	26%
human epidermal growth factor receptor 2 (HER2) status	Pos	56	8%
	Neg	437	66%
	Unknown	170	26%
Surgery type	Mastectomy	208	31%
	Lumpectomy	455	69%
neoadjuvant chemotherapy	Yes	122	18%
	No	541	82%
adjuvant chemotherapy	Yes	148	22%
	No	515	78%

Table 2: Characteristics of the breast cancer population and bariatric population with and without HRQoL (number of patients en percentages of total)

** No large imbalances between patients having and not having missing data for all baseline variables except age were found. Lower age was significantly associated with the likelihood of having missing data (p = 0.02).*

Outcome indicators over time

Table 3 describes the crude percentages of patients achieving the health outcome indicator and resulting outcome per year quarter and in total within the different populations.

Population	Outcome indicator	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Total
Baratric care (n=856)	Re-operation	105/2	129/2	90/2	130/3	85/4	54/0	171/2	77/0	**841/15**
		98%	98%	98%	98%	96%	100%	99%	100%	***98%***
	Deficiency	83/24	96/34	64/28	89/44	59/30	39/15	127/45	61/16	**618/236**
		78%	74%	70%	67%	66%	72%	74%	79%	**72%**
	Re-admission	105/2	129/2	90/2	128/5	88/1	54/0	167/6	76/1	**837/19**
		98%	98%	98%	96%	99%	100%	97%	99%	**98%**
	Admission time	102/5	125/6	87/5	130/3	86/3	52/2	162/11	74/3	**818/38**
		95%	95%	95%	98%	97%	96%	94%	96%	**96%**
	ER visit	101/6	121/10	88/4	122/11	81/8	52/2	160/13	74/3	**799/57**
		94%	92%	96%	92%	91%	96%	92%	96%	**93%**
	TWL (total weight loss)	104/3	123/8	80/12	122/11	84/5	52/2	165/7	77/0	**807/48**
		97%	94%	87%	92%	94%	96%	96%	100%	**94%**
	Survival	107/0	130/1	92/0	133/0	89/0	54/0	172/1	77/0	**854/2**
		100%	99%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**72/35**	**81/50**	**47/45**	**73/60**	**50/39**	**34/20**	**107/66**	**56/21**	**520/336**
		67%	**62%**	**51%**	**55%**	**56%**	**63%**	**62%**	**73%**	**61%**
Bariatric including HRQoL care (n=270)	Re-operation	41/2	82/0	56/1	86/2	- /-	- /-	- /-	- /-	**265/5**
		95%	100%	98%	98%	-	-	-	-	**98%**
	Deficiency	32/11	64/18	41/16	60/28	- /-	- /-	- /-	- /-	**197/73**
		74%	78%	72%	68%	-	-	-	-	**73%**
	Re-admission	42/1	82/0	55/2	86/2	- /-	- /-	- /-	- /-	**265/5**
		98%	100%	96%	93%	-	-	-	-	**98%**
	Admission time	40/3	81/1	56/1	86/2	- /-	- /-	- /-	- /-	**263/7**
		93%	99%	98%	98%	-	-	-	-	**97%**
	ER visit	42/1	76/6	53/4	82/6	- /-	- /-	- /-	- /-	**253/17**
		98%	93%	93%	93%	-	-	-	-	**94%**
	TWL (total weight loss)	43/0	80/2	52/5	80/8	- /-	- /-	- /-	- /-	**255/15**
		100%	98%	91%	91%	-	-	-	-	**94%**
	HRQoL	42/1	80/2	53/4	82/6	- /-	- /-	- /-	- /-	**257/13**

		98%	98%	93%	93%	-	-	-	-	**95%**
	Survival	43/0	82/0	57/0	88/0	- /-	- /-	- /-	- /-	**270/0**
		100%	100%	100%	100%	-	-	-	-	**100%**
	Resulting outcome * 100%	**29/14**	**56/26**	**31/26**	**48/40**	**- /-**	**- /-**	**- /-**	**- /-**	**164/106**
		67%	**68%**	**54%**	**55%**	**-**	**-**	**-**	**-**	**61%**
Breast cancer care (n=663)	Re-operation	79/3	55/6	77/3	75/6	88/7	86/5	85/3	83/2	**628/35**
		96%	90%	96%	93%	93%	95%	97%	98%	**95%**
	Survival	82/0	60/1	80/0	81/0	94/1	90/1	87/1	85/0	**659/4**
		100%	98%	100%	100%	99%	99%	99%	100%	**99%**
	Surgical margins	75/7	57/4	74/6	74/7	85/10	87/4	76/12	81/4	**609/54**
		91%	93%	93%	91%	89%	96%	86%	95%	**92%**
	Recurrance	82/0	61/0	80/0	81/0	95/0	91/0	87/1	85/0	**662/1**
		100%	100%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**73/9**	**51/10**	**72/8**	**70/11**	**78/17**	**81/10**	**72/16**	**79/6**	**576/87**
		89%	**84%**	**90%**	**86%**	**82%**	**89%**	**82%**	**93%**	**87%**

Table 3: Number (successful / not successful) and percentage of patients achieving the respective Health outcome indicator per year, quarter within the different populations.

Bariatric outcomes

In the bariatric, all clinical indicators scored above 90% except the deficiency indicator, which scored 73%. Final RO was 0.61, (range 0.51- 0.73). For the Bariatric population including HRQoL RO was 0.61, range(0.54 – 0.68). During the same period, RO was 0.59 in the bariatric population excluding HRQoL. The higher RO values in the Bariatric population including HRQoL were mainly based on a higher percentage of patients achieving the TWL and deficiency indicators.

Breast cancer outcomes

In the breast cancer population RO was 0.87, range (0.82 - 0.93). The surgical margins indicator was least successful, with 92% of patients achieving it. The recurrence indicator was the most successful. It was failed by one patient in 2020 Q3.

QCI values

[Insert figure 1 here]

Figure 1. Case mix adjusted Resulting outcome (panel 1A, 1B), ATC (panel 2A, 2B) and QCI values (panel 3A, 3B) over time for both populations.

Figure 1 displays case-mix adjusted RO (panel 1A, 1B), ATC (panel 2A, 2B) and resulting QCI values (3A and 3B). Supplementary results comparing RO, ATC and QCI values including and excluding cost outliers are attached in technical supplements 1 (Breast cancer) and 2 (Bariatric population).

Bariatric RO, Cost and QCI values

For the bariatric population RO, ATC and QCI values are presented twice, once including the HRQoL indicator and once for the total bariatric population. As presented in panel 1A, RO values of the Bariatric population including HRQoL are higher compared to the total Bariatric population. Because ATC of both groups are similar (Panel 2A), QCI values of the Bariatric population including HRQoL are higher in 2019 Q2 and Q3. Overall, because ATC of the bariatric population has a low variance (SD = €230.42) deviations in QCI values are mostly due to changes in RO values. Excluding outliers had little impact on RO and QCI values for both groups. ATC values were slightly lower (AVG € 8,388.26 instead of €8,833.55) and less variable (a decrease in Inter Quartile Range (IQR) of € 253.31).

Breast cancer RO, Cost and QCI values

The results of the breast cancer population show that QCI (panel 3B) values can be impacted by a combination of both ATC (panel 2B) and RO (panel 1B). For the breast cancer population this is especially true in 2019 Q3 and 2020 Q1. In 2019 Q3 QCI values were highest due to a combination of low costs and high RO values. The opposite is true for 2020 Q3 were a combination of high ATC and low RO values resulted in the lowest QCI value. Excluding outliers impacted the ATC of the breast cancer population predominantly in 2020, producing higher average QCI values (8.08 instead of 6.70) in that period.

Costs per population per outcome Category

Table 4 describes the characteristics of the cost distributions per outcome category for each population.

Population	Outcome category	Number of patients	Average Costs	Standard Deviation Costs	Interquartile Range (IQR) of Costs	P Value
Bariatric care	Admission time failed	21	€ 11,854.96	€ 4,535.65	€ 3,465.92	< 0.01
	Deficiency failed	192	€ 8,452.58	€ 1,457.45	€ 1,603.95	
	ER visit failed	25	€ 8,867.37	€ 1,778.55	€ 1,697.46	
	Other failed	66	€ 12,871.99	€ 10,290.17	€ 3,915.20	
	Textbook outcome	520	€ 8,470.70	€ 1,450.37	€ 1,599.11	
	TWL failed	32	€ 8,603.64	€ 1,448.56	€ 1,685.98	
Bariatric care including HRQoL	HRQoL Failed	6	€ 9,267.24	€ 3,587.81	€ 1,754.82	0.02
	Deficiency failed	54	€ 8,404.37	€ 1,173.08	€ 1,236.08	
	ER visit failed	7	€ 8,661.00	€ 888.35	€ 1,192.50	
	Other failed	30	€ 12,189.78	€ 1,0887.56	€ 2,235.78	
	Textbook outcome	164	€ 8,483.20	€ 1,263.51	€ 1,536.37	
	TWL failed	9	€ 8,165.08	€ 1,029.86	€ 1,733.97	
Breast cancer care	Other failed	11	€ 18,231.83	€ 8,878.90	€ 12,516.42	< 0.01
	Positive Margins failed	47	€ 14,772.80	€ 10,234.77	€ 7,093.75	
	Reoperation failed	29	€ 18,792.08	€ 12,317.22	€ 10,084.12	

	Textbook outcome	576	€ 12,277.29	€ 10,273.12	€ 6,666.06	

Table 4: Descriptive measures of the total costs per outcome category for each population. P values refer to the overall difference in total costs across outcome categories within populations.

Costs of care per outcome category for the bariatric population

For the bariatric population, patients in the Other failed and Admission time failed categories had high average costs of care, compared to the other categories. The Other failed category also had the highest standard deviation and IQR. For the bariatric population including HRQoL, patients in the Other failed category had the highest average costs of care whereas patients in the TWL failed category had the lowest average costs. Total costs by outcome category differed significantly for both populations.

Costs of care per outcome category for breast cancer population

For breast cancer patients, the average costs of the Reoperation failed and Other failed outcome categories were comparable. Patients in the Textbook outcome category had the lowest average costs of care. Again total costs by outcome category differed significantly.

Discussion

In this proof of concept study, we developed the QCI model in collaboration with physicians, patient representatives and healthcare managers based on VBHC principles. The QCI model suits the need for monitoring healthcare costs and health outcomes, and thereby the evaluation and quality assessment of healthcare interventions or quality improvements on an institutional level. The framework provides management information on (patient perceived) health outcomes and costs in a single metric and underlying components, for clinicians and healthcare management.

The results show that the QCI framework is sensitive to changes in ATC and RO. A strength of the QCI framework is that routinely collected cost and outcome data from EMR and PROMs software are directly available for QCI analysis. Furthermore, the QCI framework has a high level of flexibility because health gains can be based on a large variety of outcomes, preferably those outcomes that cover all main health effects associated with the care path. This flexibility in outcomes also makes the QCI framework applicable for a variety of medical conditions. These findings indicate that the framework is suitable for monitoring performance of care in terms of outcomes and costs in clinical practice, on an institutional level. Using the framework in a plan do act check (PDCA) cycle, with or without using the underlying indicator and cost data, should help evaluate results and guide continued improvement processes [24].

Not all outcome categories equally affected hospital based costs of care. Failure of outcome indicators with regard to surgery were associated with higher costs. These results can be explained by the direct impact of surgical procedures on hospital based costs [25]. However no direct impact of the deficiency and TWL indicators on hospital based costs of care was visible. On the other hand, deficiencies can lead to the development of metabolic bone diseases in the long-term [26] and obesity is a known risk for coronary heart disease [27]. The follow-up period of one year might not have been sufficient to investigate the expected increase in cost due to these complications. Investing in adherence to follow up could result in a higher percentage of patients passing the TWL and deficiency indicators thereby possibly preventing these long-term costs [28]. Investing in adherence to follow up could therefore, in short term QCI analysis, lead to higher costs and a higher RO. This indicates that short term QCI values can either improve or decrease depending on whether the gain in RO outweighs the gain in costs. In a long term QCI analysis, QCI values could improve as additional costs to treat the aforementioned complications could be avoided and RO increases. Different follow-up periods could therefore result in different QCI values.

VBHC, CEA and QCI all agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However both VBHC and CEA require complex calculations to summarize outcomes [7, 9,15,16, 17]. In contrast, in QCI the RO parameter is an understandable statistic summarizing outcomes. Also, in the basis, VBHC and CEA include social as well as direct healthcare costs. QCI, in this analysis, is limited to costs incurred at the healthcare provider. This matches the clinician and managerial perspective. Alternatively, the model could also include out-of-hospital costs and non-medical costs if this is relevant for hospital management. Finally, both CEA and VBHC recommend analysis of the full cycle of care. In QCI different follow-up period are available, because short-run or medium term analysis can provide valuable information for managerial purposes.

The definition of TO as “all clinical outcome indicators are met” gives healthcare providers a pragmatic method to summarize outcomes. However a limitation of this binary scoring model is that value is only created when all health indicators are met (1), and no value is created when at least one of the indicators is failed (0). In the first case, when all indicators are passed, the patient can still perceive the treatment as less then optimal. In the latter case, the patient can view the treatment (at least partially) as a success. The binary scoring rule could therefore result in an overestimation of value, but is more likely to lead to an underestimation of value. An alternative approach could be to define an outcome measure with a continuous score that varies between completely suboptimal outcome (0) and completely optimal outcome (100), with or without assigning different weights to different outcome indicators. Another limitation is missing data. When data from one indicator is missing and the other indicators are passed, QCI values are not defined. Because the QCI framework can give an under- as well over-estimation (or no estimation in the case of missing data) of value on the micro level(physician-patient encounter) [6], the framework isn’t applicable at this level. The QCI model can give

valuable information on an institutional level as it summarizes group outcomes and costs in an understandable fashion.

Areas of future research include defining upper and lower margins for outcome, costs and QCI values to guide continued improvement processes. Because as time passes chances of failing or succeeding an indicator can vary [29], future research should investigate RO and TO values over multiple follow-up periods. Comparing hospital performance using the QCI framework could be helpful for optimizing QCI values and underlying costs and outcome results [30]. Finally, the QCI framework should be applied to more medical conditions, in chronic and acute settings to study the generalizability of the properties of the QCI model.

Conclusions

This proof of concept study showed that the QCI framework is effective for monitoring the performance of care paths in terms of costs and health outcomes on an institutional level. An overall impact of health outcome indicators on hospital based costs of care is found. Also, some indicators, or combination of indicators, impact costs more than others.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval statements that refer to your institution

Because the study retrospectively evaluated care as usual a Medical research Ethics Committee review isn't obliged under Dutch Legislation. The Institutional Review Board of the Franciscus Gasthuis & Vlietland hospital, named Advies Commissie Wetenschap (ACW) reviewed and waived the study protocol (ref. 2023-002). The ACW stated that retrospective collection of informed consent was not required for this registry-based study. The effort to do so would be disproportionate due to the number of patients in the study and the fact that the treatment occurred some time ago. The study was conducted in accordance with the Declaration of Helsinki.

Contributorship statement

The study was conceived by WHP and JB. Data collection, analysis were performed by WHP. The manuscript was drafted by WHP and EB. Methodological and statistical integrity was checked by EB. SB, TMALK, and AEAMvW provided feedback on the manuscript. All authors read and approved the final manuscript.

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Not applicable

Availability of data and materials

The datasets used in this study are not publicly available under the Dutch privacy legislation. Anonymized datasets can be made available from the corresponding author on reasonable request

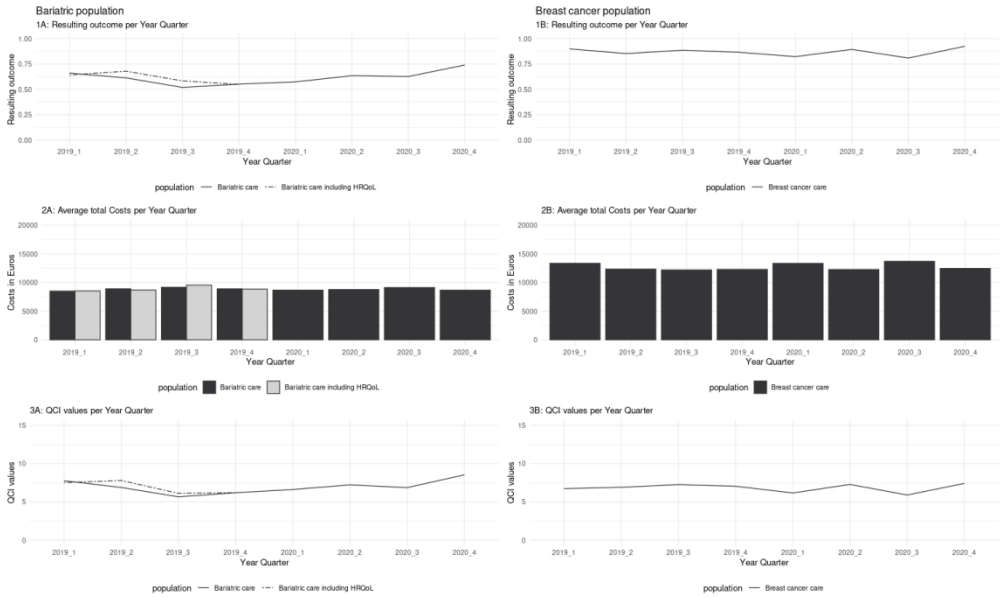


Figure 1. Case mix adjusted Resulting outcome (panel 1A, 1B), average total costs (panel 2A, 2B) and QCI values (panel 3A, 3B) over time for both populations.

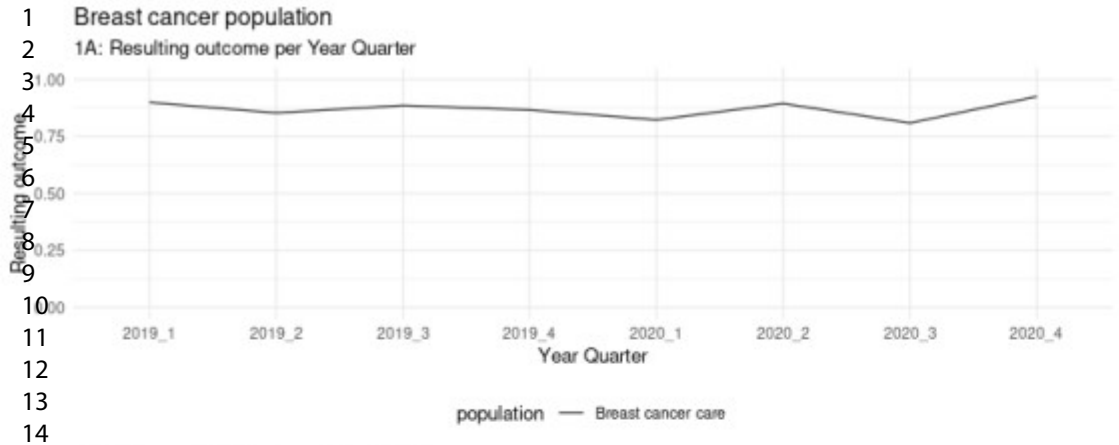
1134x682mm (34 x 34 DPI)

Appendix 1: Health outcome indicators

Patient population	KPI	Description	Success measure
Bariatric	Re-operation	The following surgeries within 30 days of the primary surgery were taken into account: - Operative treatment for esophageal perforation - Endoscopic extension gastric bypass - Endoscopic sleeve and Pouch bypass - Endoscopic gastronomy - Overstitching stomach perforation (open/ endoscopic) - Endoscopic small intestine resection - Endoscopic intestinal anastomosis - Overstitching intestinal perforation (open / laparoscopic) - Cholecystectomy laparoscopic - Laparotomy - Closure of the Petersen mesenteric defect - Bleeding within 24 hours of the primary surgery - Incisional hernia (open / laparoscopic)	If a surgery was performed within 30 days following the primary surgery, the treatment failed to meet the clinical outcome indicator.
	Deficiency	The following blood levels were measured: - Ferritine (22 µg/L) - Active B12 (32 pmol/L) - Folate (7 nmol/L) - Vitamin B1 (70 nmol/L) - Vitamin B6 (35 nmol/L) - Vitamin D (50 nmol/L)	The blood level measure after 9 months and before 21 months closed to one year mark post-surgery was used as the measure to decide if the patient had deficiencies. If in this measure any of the blood levels were below the norm levels the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	Hospital admissions within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation	If there was an additional unplanned admission the treatment was stated to have failed to meet the clinical outcome indicator.

		- Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	
	Admission time	Admission time directly following the surgery	If admission time of the primary admission exceeded 72 hours treatment was stated to have failed to meet the clinical outcome indicator.
	ED	Emergency deparment visits within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation - Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	If there was an emergency department visit within 30 post surgery the treatment failed to meet the clinical outcome indicator.
	TWL (total weight loss)	(Initial weight – current weight) / initial weight	If TWL exceeded 20% in a period of 455 days following the surgery the clinical outcome indicator was considered successfully passed.

Breast Cancer	Re-operation	All surgeries due to infections or bleeding as a result of the primary surgery:	Once a patient received a surgery due to infections or bleeding the treatment was stated to have failed to meet the clinical outcome indicator.
	Surgical Margins	All patients who received surgery (lumpectomy or mastectomy) due to close or positive margins	Once a patient did receive surgery the treatment the treatment was stated to have failed to meet the clinical outcome indicator. If margins did not need a further surgery the clinical outcome indicator was considered to be successfully passed.
	Recurrence	All who had a recurrence of the primary tumor. It was considered all these patients did receive surgery (either an mastectomy or mastectomy).	Once the patient received surgery to treat the recurrence the treatment the treatment was stated to have failed to meet the clinical outcome indicator.


Breast cancer population
1A: Resulting outcome per Year Quarter
Resulting outcome
1.00
0.75
0.50
0.25
0.00
2019_1
2019_2
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2020_1
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2020_3
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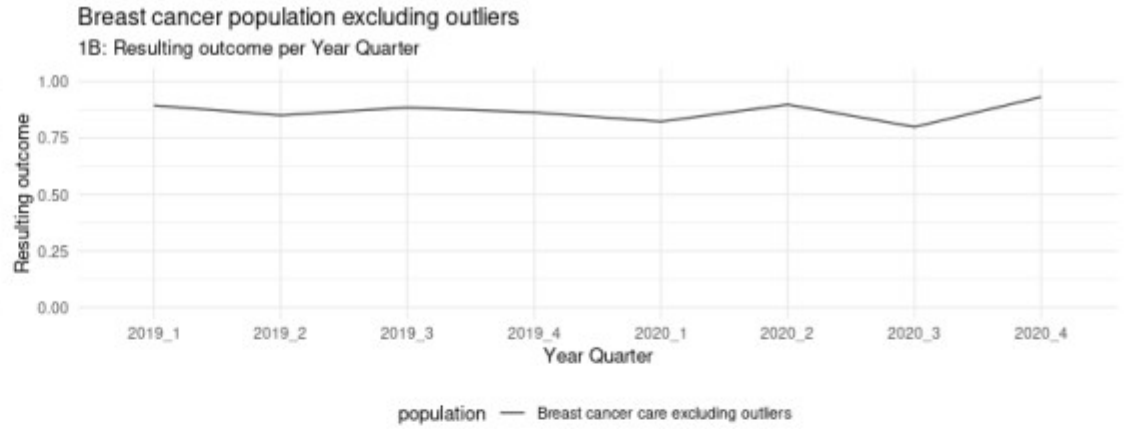
Year Quarter
population
Breast cancer care


Breast cancer population excluding outliers
1B: Resulting outcome per Year Quarter
Resulting outcome
1.00
0.75
0.50
0.25
0.00
2019_1
2019_2
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2019_4
2020_1
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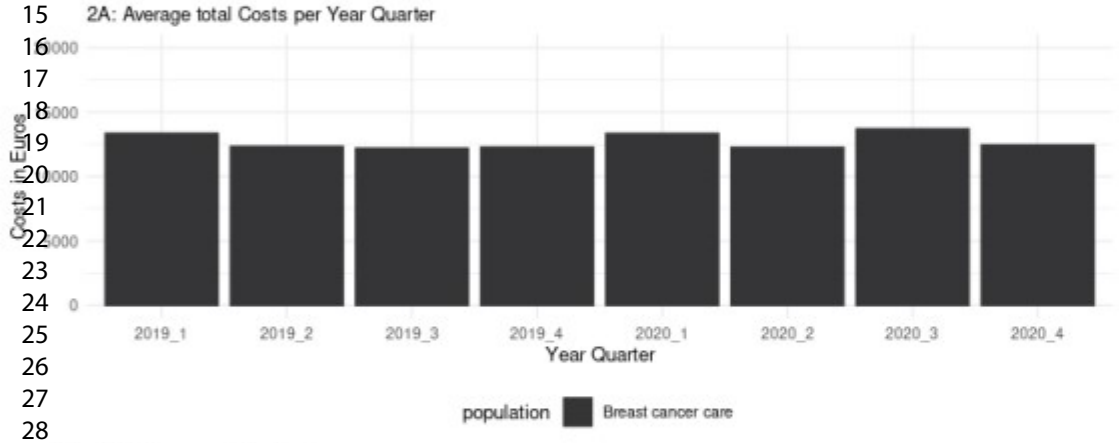
2020_3
2020_4
Year Quarter
population
Breast cancer care excluding outliers


2A: Average total Costs per Year Quarter
Costs in Euros
20000
15000
10000
5000
0
2019_1
2019_2
2019_3
2019_4
2020_1
2020_2
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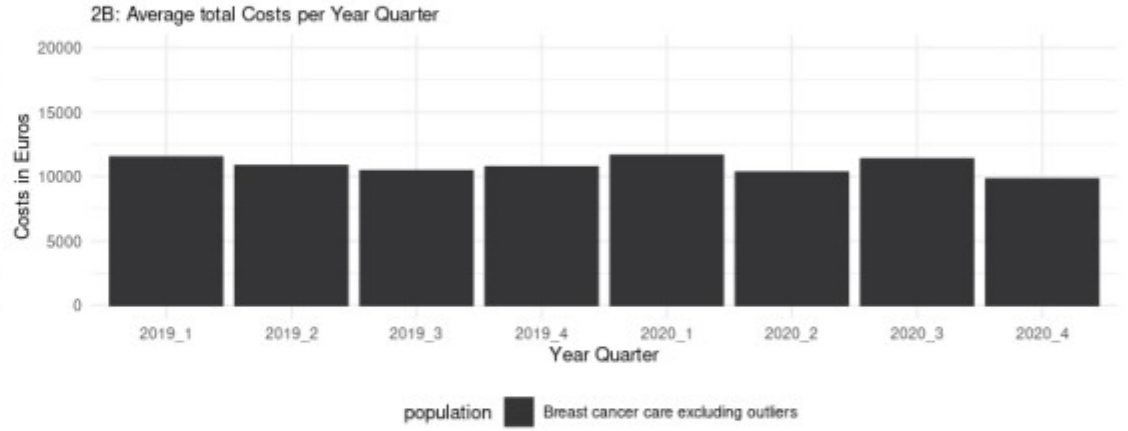
2020_4
Year Quarter
population
Breast cancer care


2B: Average total Costs per Year Quarter
Costs in Euros
20000
15000
10000
5000
0
2019_1
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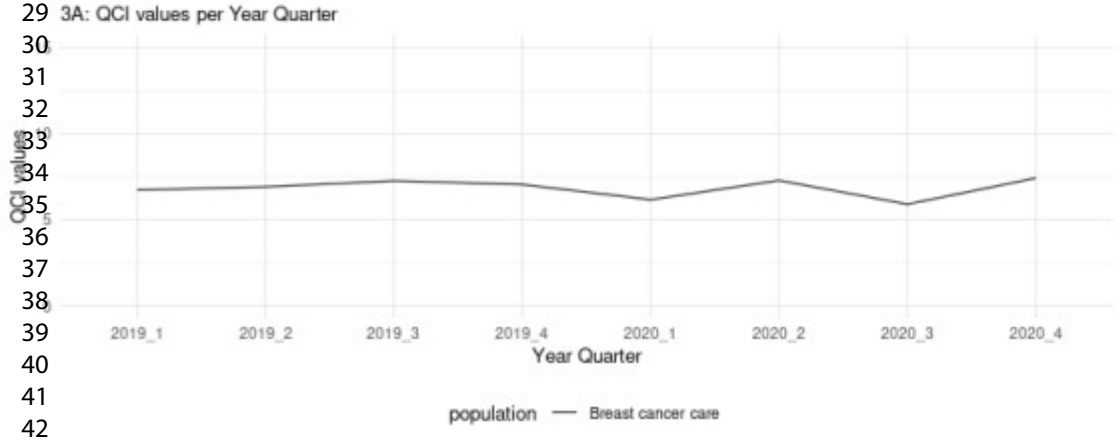
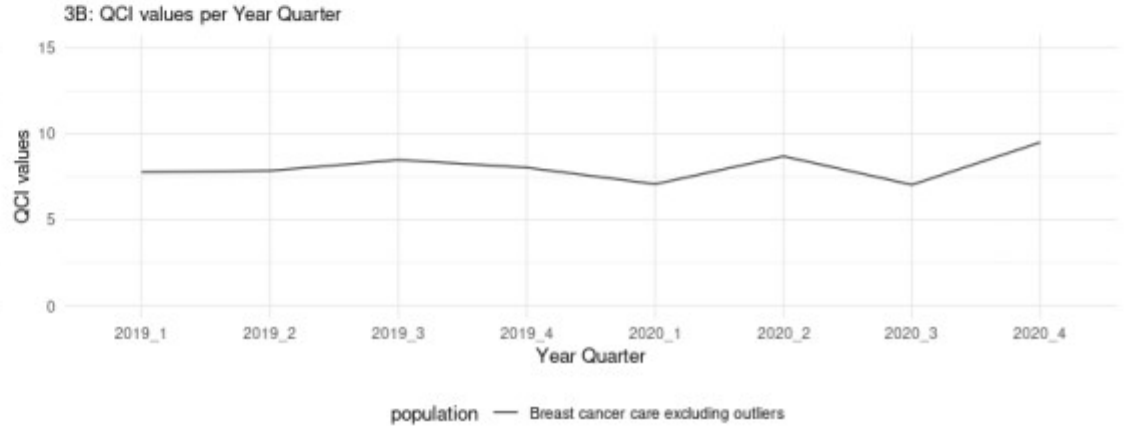
2019_3
2019_4
2020_1
2020_2
2020_3
2020_4
Year Quarter
population
Breast cancer care excluding outliers


3A: QCI values per Year Quarter
QCI values
2019_1
2019_2
2019_3
2019_4
2020_1
2020_2
2020_3
2020_4
Year Quarter
population
Breast cancer care


3B: QCI values per Year Quarter
QCI values
15
10
5
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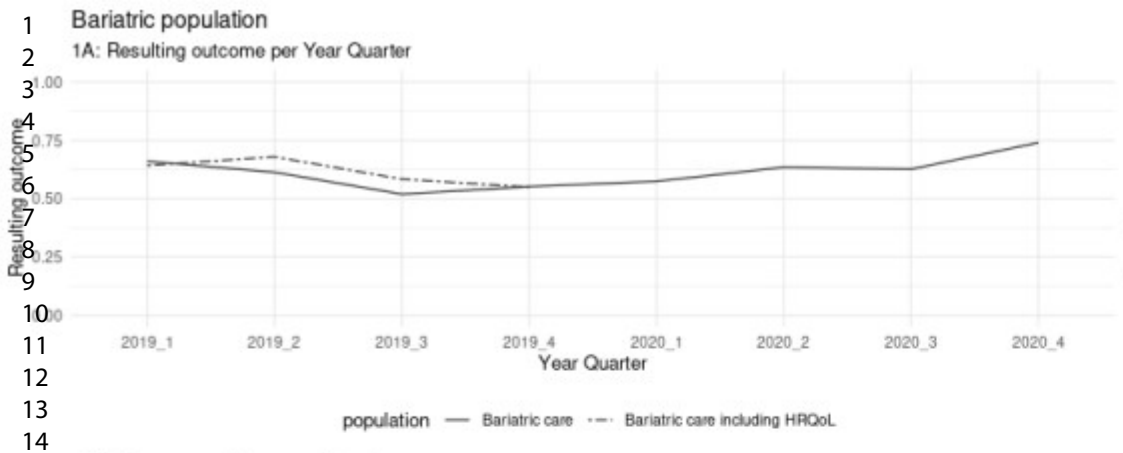
Year Quarter
population
Breast cancer care excluding outliers


Bariatric population
1A: Resulting outcome per Year Quarter
Resulting outcome
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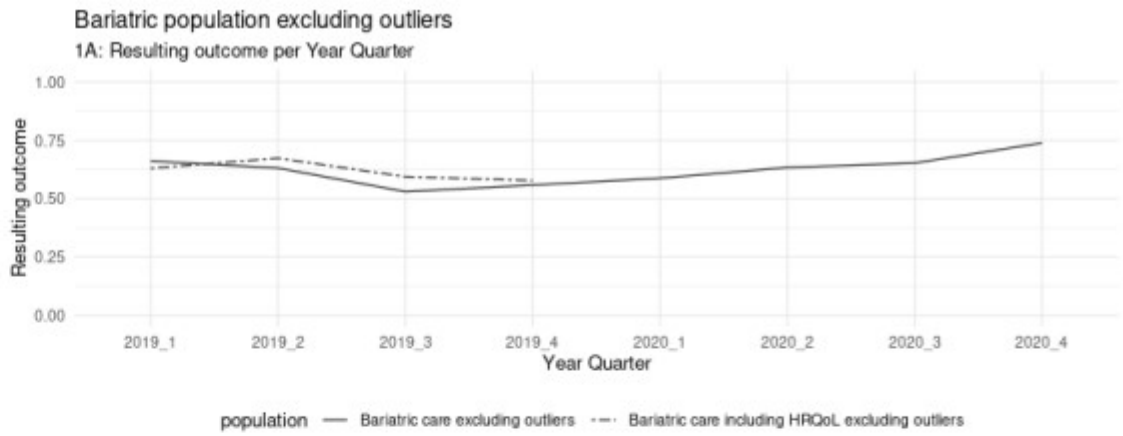
Year Quarter
population
Bariatric care
Bariatric care including HRQoL


Bariatric population excluding outliers
1A: Resulting outcome per Year Quarter
Resulting outcome
1.00
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0.50
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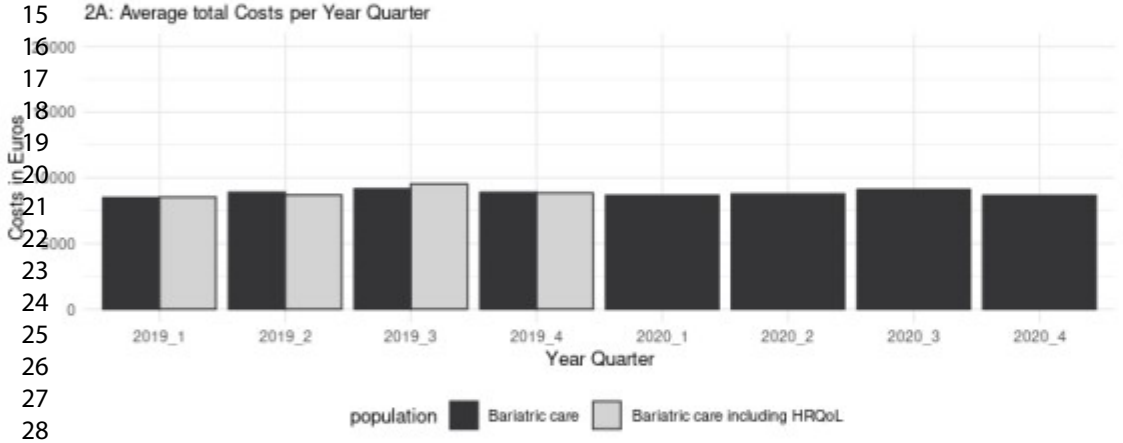
Year Quarter
population
Bariatric care excluding outliers
Bariatric care including HRQoL excluding outliers


2A: Average total Costs per Year Quarter
Costs in Euros
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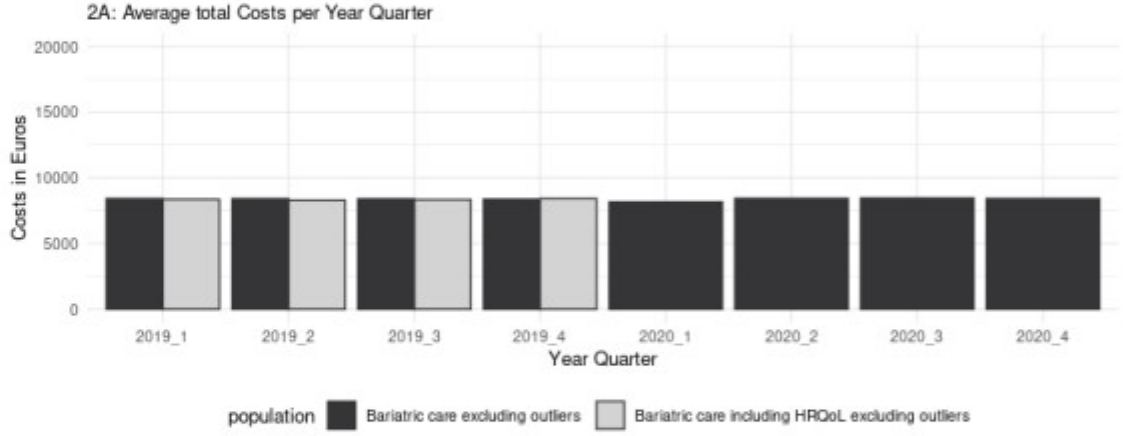
Year Quarter
population
Bariatric care
Bariatric care including HRQoL


2A: Average total Costs per Year Quarter
Costs in Euros
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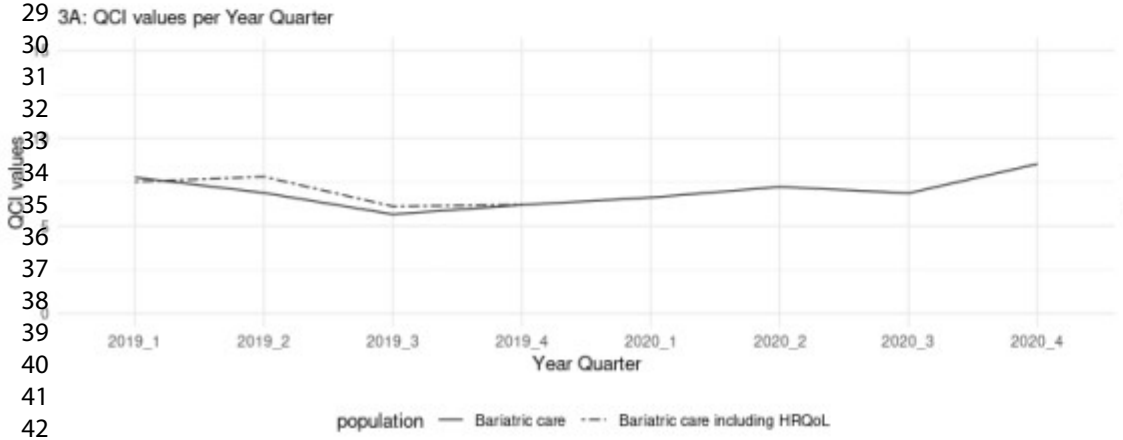
population
Bariatric care excluding outliers
Bariatric care including HRQoL excluding outliers


3A: QCI values per Year Quarter
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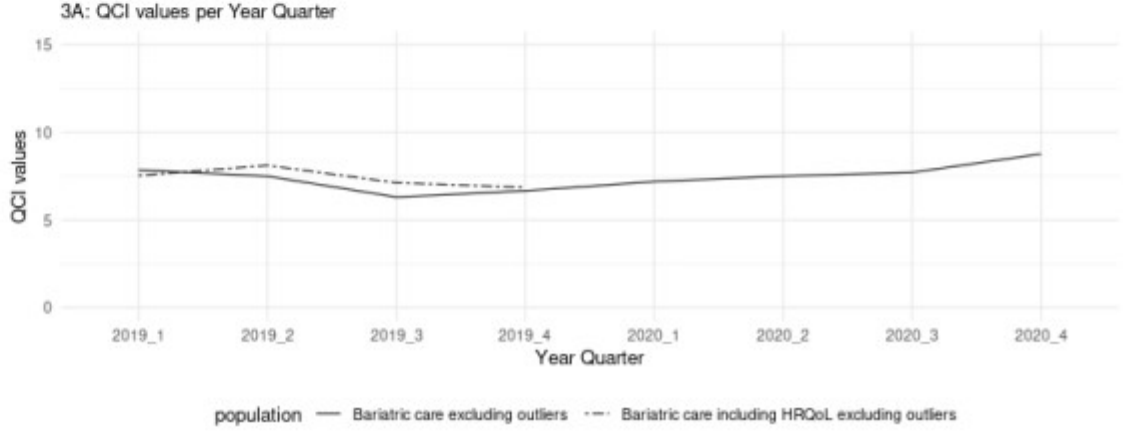
population
Bariatric care
Bariatric care including HRQoL


3A: QCI values per Year Quarter
QCI values
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2020_1
2020_2
2020_3
2020_4
Year Quarter
population
Bariatric care excluding outliers
Bariatric care including HRQoL excluding outliers

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title page
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4&6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4&5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5&6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6&7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	10 up to 13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	13
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Is the QCI framework suited for monitoring outcomes and costs in a teaching hospital using Value Based Healthcare principles?: A retrospective cohort study

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Is the QCI framework suited for monitoring outcomes and costs in a teaching hospital using Value Based Healthcare principles?: A retrospective cohort study

Veghel W.H.P. van [1]* Msc, Dijk S.C. van MD PhD[2], Klem T.M.A.L MD PhD.[3], Weel A.E.A.M. MD PhD[4,5], Bügel JB.Msc[1], Birnie E. PhD [6,7]

1. Department of Finance and Control, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
2. Department of Geriatrics, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
3. Breast Clinic, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
4. Department of Rheumatology, Maasstad Hospital, Rotterdam the Netherlands
5. Erasmus School of Health Policy & Management (ESHPM), Erasmus University Rotterdam, Rotterdam the Netherlands
6. Franciscus Academy, Franciscus Gasthuis en Vlietland Hospital, Rotterdam the Netherlands
7. Department of Genetics, UMC Groningen, University of Groningen, Groningen the Netherlands

Address for contact:
W.H.P. van Veghel MSc

Address: Vlietlandplein 2, Schiedam, the Netherlands

Zip code: 3118 JH

M: +31 612679714
E: W.veghel@franciscus.nl

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Value Based Healthcare, Health outcomes, Healthcare costs, Evaluation of care, Care pathways

Word count

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Abstract

Objectives

To develop a pragmatic framework, based on value based healthcare principles, to monitor health outcomes per unit costs on an institutional level. Subsequently we investigated the association between health outcomes and healthcare utilization costs.

Design

A retrospective cohort study

Setting

A teaching hospital in Rotterdam, The Netherlands

Participants

The study was performed in two use cases. The bariatric population contained 856 patients of which 639 were diagnosed with Morbid obesity BMI < 45 and 217 were diagnosed with Morbid obesity BMI >= 45. The breast cancer population contained 663 patients of which 455 received a lumpectomy and 208 a mastectomy.

Primary and secondary outcome measures

The quality cost indicator (QCI) was the primary measures and was defined as

QCI = (resulting outcome * 100) / average total costs (per thousand Euros).

Where average total costs entail all healthcare utilization costs with regard to the treatment of the primary diagnosis and follow-up care. Resulting outcome is the number of patients achieving textbook outcome (passing all health outcome indicators) divided by the total number of patients included in the care path.

Results

The breast cancer and bariatric population had highest resulting outcome values in 2020 Q4, 0.92 and 0.74 respectively. The average total costs of the bariatric population remained stable (avg, € 8,833.55, min € 8,494.32, max € 9,164.26). The breast cancer population showed higher variance in costs (avg, € 12,735.31 min € 12,188.83, max € 13,695.58). QCI values of both populations showed similar variance (0.3 and 0.8). Failing health outcome indicators was significantly related to higher hospital based costs of care in both populations ($P < 0.01$).

Conclusions

The QCI framework is effective for monitoring changes in average total costs and relevant health outcomes on an institutional level. Health outcomes are associated with hospital based costs of care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study included multiple populations with a large number of patients followed over a prolonged period.
- In the study multiple clinical indicators and patient reported outcomes were defined to calculate Textbook and resulted outcome.
- To create a pragmatic framework a binary outcome measure was defined. On a patient-physician level this can lead to an over- or under estimation of value.

Introduction

Medical costs have risen rapidly in recent decades, particularly in developed countries. This increase even exceeded the growth of the Gross Domestic Product (GDP) [1], implying that an increasing percentage of GDP has been spent on healthcare. Simultaneously, the gain in life expectancy was marginal and perceived health status remained approximately stable [2]. Also changing population demographics, such as aging [2] and an increasing prevalence of multimorbidity [3] and healthcare innovations [4] contributed to the rise in healthcare costs. Therefore an improved health-related effectiveness evaluation model is required to achieve affordable, high quality care in the future.

Cost Effectiveness Analysis (CEA) is the leading evaluation model to aid priority setting in healthcare budgeting [5] on the macro, national, level [6]. CEA quantifies differences in costs and outcomes for each new medical intervention compared to care as usual. In CEA value is usually defined as health-related effectiveness, and operationalized using the Quality Adjusted Life Years (QALYs) metric, while costs include healthcare and societal expenditure [7].

CEA is less suitable for priority setting on a meso, institutional, level [6]. In CEA, the QALY model includes patients' life span adjusted for health-related quality of life (HRQoL), which is based on patients' generic health status [7]. In daily practice however, this data is not available, nor easily obtained at the institutional level. Also data regarding social expenditure is neither present nor manageable on an institutional level. Furthermore, results in CEA can be hard to interpret for clinicians and healthcare managers. This makes it difficult to manage healthcare costs and health outcomes using the CEA framework.

In addition because CEA analysis are based on the patients lifespan, either the remaining lifespan should be estimated, or the analysis can only be performed after the patient is deceased. Combining quality of life and quantity of life in a single metric can then be challenging. Both are different units, one qualitative and the other qualitative, and so are not easily summarized in a single statistic.

In 2006 Porter and Teisberg proposed the concept of Value Based Healthcare (VBHC) [8]. VBHC describes value as patient centered health outcomes per unit costs. CEA and VBHC both agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However in CEA health outcomes are based on generic HRQoL measures whereas in VBHC relevant outcomes have been defined as disease or care path specific indicators. The latter approach makes VBHC more feasible at the institutional level [6], because care paths are well defined and disease specific clinical outcome measures are registered in the electronic medical records (EMR).

For benchmarking between institutions and measuring outcomes within an institution over time, health outcomes need to be standardized [10]. The International Consortium for Health Outcomes Measurement (ICHOM) has therefore published several sets of "patient-centered outcome measures" [11,12,13,14].

Because health outcomes are anyhow disease specific, they are inherently multidimensional and can vary between patients and over time. Several VBHC studies applied or proposed a multi-criteria analysis to summarize multiple outcome indicators into one metric [9,15,16, 17]. Yet, there is no standardized operational VBHC 'common metric system' that aggregates care path specific outcomes over time. Also for most indicators there is no clear criterion when such a relevant outcome is either fully achieved, failed or partially achieved. However if a single VBHC metric produces understandable results, it could support managerial decision making on an institutional level.

Because current frameworks have a high complexity and limited applicability for priority setting on an institutional [6] level, we propose a more pragmatic framework that includes costs and outcomes of care paths over time. Such a framework can be used for monitoring care paths, identification of suboptimalities within care paths, and serve as reference for quality improvement programs and quality improvement reports at the institutional level. Furthermore, we will investigate if the framework can be utilized for clinical and managerial decision making and/or quality of care assessments in daily clinical practice. Finally, we will analyze which (combination of) health outcomes are associated with increases in healthcare costs.

Methods

Patient population

This proof of concept study was a retrospective, real world cohort study, performed in two use cases, namely: bariatric surgery and breast cancer surgery in Franciscus Gasthuis & Vlietland Hospital, a large medical teaching hospital in Rotterdam, The Netherlands.

Bariatric population

For the bariatric population, all aged >= 18 year older patients diagnosed with morbid obesity (Body Mass Index (BMI) >= 40) , treated with gastric bypass or a gastric sleeve resection surgery in 2019 or 2020 were included. Patient who received bariatric surgery in previous years were excluded because it was unclear if/ when a new primary treatment started and the previous treatment stopped.

Breast cancer population

For the breast cancer population, all patients aged >= 18 year older diagnosed with malignant mammary neoplasm and treated with a mastectomy, wide local excision, and possibly a breast reconstruction in 2019 or 2020 were included. Patients with stage IV breast cancer at the start of the care path were excluded, because they received palliative care. Also patients with any breast cancer diagnosis prior to the study were excluded because it was unclear if/ when the new primary treatment started and the previous treatment stopped.

Quality Cost Indicator Model

In collaboration with physicians, patient representatives and healthcare managers we developed a model to support managerial decision making based on VBHC principles: the quality cost indicator (QCI) model. This model was built on five concepts: textbook outcome (TO) resulting outcome (RO) , average total costs (ATC), QCI date and QCI period. Each of these concepts are described below.

Textbook Outcome*:* Textbook outcome (TO) [18] is accomplished when patients meet all health outcome indicators, as defined for a specific care path. For example, survival should and HRQoL can be a part of TO.

Resulting outcome*:* The resulting outcome (RO) rate refers to the number of patients who achieved TO divided by the total number of patients included in the care path. RO varies between 0 and 1.

Average total costs: Total costs (TC) are calculated as the sum of the healthcare utilization costs incurred at the healthcare provider. These costs include, the costs of the primary treatment plus any costs following the treatment of symptoms, adverse events or comorbidities of the evaluated patients. The (ATC) equals the TC divided by the total number of patients included in the care path.

QCI date: The TO, RO and ATC parameters are attributed to a QCI date. This is a specific date for each patient, such as the surgery date or date of diagnosis depending on the intervention that will be evaluated.

QCI period: The QCI period is a follow-up period in which the outcomes (TO and RO) and costs (ATC) should be determined. All costs, RO and TO should be considered from the start of the care path (which can occur before the QCI date) until the end of the QCI period. The length of the QCI period can vary according to the goal of the analysis. For example, short term cost analysis and managerial decisions often require a short QCI period while treatment effectiveness from a the patients' and/ or physicians' perspective can require a longer QCI period.

With these five concepts in mind, QCI values can be calculated as follows:

QCI = (resulting outcome * 100) / average total costs (per thousand Euros)

Outcome indicators

The following outcome indicators were defined to calculate RO over time. Data regarding outcome indicators were extracted from the EMR.

Bariatric outcomes

Because there is no VBHC standard outcome indicator set for bariatric surgery, outcome indicators were defined by physicians in consultation with patient representatives. This was achieved via flowtables in which patients provided feedback to physicians on what they found high quality care. Table 1 summarizes the outcome indicators for the bariatric population (Appendix 1 shows the full definitions) .

QCI values for the bariatric population were calculated twice, once including and once excluding the HRQoL indicator. QCI values including HRQoL were only calculated for surgery dates in 2019 due to data availability.

Breast cancer outcomes

Table 1 also shows the clinical outcome indicators for the breast cancer population, which were based on the ICHOM set [11] (again appendix 1 shows the full definitions). Because Patient Reported Outcome Measures (PROMs) have only been incorporated in breast cancer care since 2021, we were unable to include the HRQoL indicator.

Patient population	Clinical outcome indicator	Threshold value
Bariatric	Re-operation	If a surgery related to the bariatric treatment was performed within 30 days following the primary surgery the treatment failed to meet the clinical outcome indicator.
	Deficiency	The mineral and vitamin blood level measure after 9 month and before 21 months (local protocol) closest to one year mark post-surgery was used as the measure to decide if the patient was deficient. If in this measure any of the blood levels were below the norm level the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	If there was an additional unplanned admission related to the primary diagnosis (not as a result of an additional surgery) the treatment failed to meet the clinical outcome indicator.
	Admission time	If admission time of the admission related to the primary surgery exceeded 72 hours the treatment failed to meet the clinical outcome indicator.
	Emergency Department visit (ED)	If there was an ED visit related to the bariatric treatment within 30 days post-surgery the treatment failed to meet the clinical outcome indicator.
	Total weight loss (TWL)	If TWL exceeded 20% within 455 days (local protocol) following the surgery the clinical outcome indicator was considered successfully passed.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.
	HRQoL	HRQoL was measured for the bariatric population using the RAND-36 scale of physical health [19]. When the physical health scale one year post-surgery was improved or a least equal to the physical health scale pre-surgery, the HRQoL indicator was considered to be successfully passed.
Breast Cancer	Re-operation	If a patient received a surgery due to an infections or bleeding as the result of the primary surgery the treatment failed to meet the clinical outcome indicator.
	Surgical Margins	If a patient received a re-lumpectomy due to positive surgical margins the treatment failed to meet the clinical outcome indicator.
	Recurrence	If a patient received a lumpectomy or mastectomy to treat a recurrence the treatment failed to meet the clinical outcome indicator.
	Disease specific survival	If a patient passed away during the QCI period due to the primary diagnosis the treatment failed to meet the clinical outcome indicator.

Table 1. Description of the clinical outcome indicators per population.

Health care Utilization Costs

For each patient, TC were calculated as number of activities of care * costs per unit of each activity. For example, the number of MRI scans * costs per MRI scan. Activities of care are specified according to the nationwide Dutch cost price model [20] which covers all hospital-based costs (not reimbursement fees). The Dutch cost price model relates cost per units of specific activities to the diagnosis for which the activity is performed. At one point in time, one activity can be used to treat one diagnosis. Therefore the primary and follow-up diagnosis needed to be included for all populations. All data regarding healthcare utilization costs were extracted from the financial module of the EMR.

Bariatric utilization costs

For the bariatric population, all healthcare utilization costs based on a morbid obesity diagnosis in the surgery department and on an adiposity/obesity diagnosis in the internal medicine department were included. Moreover, costs related to readmissions or ED visits within the bariatric population were included when one of the diagnoses in Appendix 1 was present.

Breast cancer utilization costs

For the breast cancer population all healthcare utilization costs based on a malignant mammary neoplasm diagnosis in the surgery department and based on a mammary malignancy diagnosis in the internal medicine department were used.

Reference prices from 2019 were used to calculate costs for both populations throughout the entire QCI period. Finally, for calculating additional costs of expensive medication, average billing prices per medication were calculated and multiplied by the number of times these were administered per patient. These costs were then added to the utilization costs of the patient to complete the full hospital based costs of care.

QCI date and period

For all populations, the QCI date was selected as the surgery date. The QCI follow-up period was set at 1 year. To include all costs of the treatment for all patients, all costs from one year prior to the QCI date (2019 or 2020) until the end of the QCI period (2020 or 2021) were included.

Outcome categorization

For analyzing the association between outcome indicators and costs, outcome indicators need to contain a minimum number of patients per outcome status (achieved / failed). Because some indicators were failed only a few times, indicators were categorized. The categories were defined such that they contained at least 5 patients.

Bariatric outcome categories

The bariatric population contained the following outcome indicator categories:

- Admission time after the primary surgery failed
- Deficiency failed
- ED visit failed
- TWL failed
- Other failed
- Textbook outcome

Each category except Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). The Other failed category contained patients who either failed the re-operation or re-admission indicator or a combination of indicators.

Due to differences in outcomes (achieved / failed outcome indicators) between the bariatric population including and excluding HRQoL, the admission time failed category was replaced by the HRQoL failed category, containing patients who only failed the HRQoL indicator, in the population including HRQoL. The Other failed category therefore contained patients who either failed the re-operation, admission time or re-admission indicator or a combination of indicators. All other outcome categories remained the same.

Breast outcome categories

For the breast cancer population, the outcome categories were as follows:

- Positive Margins failed
- Reoperation failed
- Other failed
- Textbook outcome

Again all categories except the Other failed category contained patients who only failed the respective indicator, or passed all indicators (TO). Patients in the Other failed category either failed the recurrence or survival indicators or failed multiple indicators.

Analysis

Stratification

To increase comparability of QCI values we adjusted ATC and RO values for patient characteristics using stratification.

Bariatric population

The bariatric population was stratified according to:

- Gender
- Age (</>=40 years)
- Body Mass Index (BMI) at the start of the treatment (BMI ≥45, or BMI<45).

National guidelines indicated that gender, BMI and age impact the costs and outcomes of the treatment [21]. Data of the bariatric population also showed that patients over 40 had relatively higher costs than patients under 40.

Breast cancer population

The breast cancer population was stratified for:

- Age (</>=70 years)
- Tumor, nodule, metastasis score / ductal carcinoma in situ
- Estrogen receptor status
- Human epidermal growth factor receptor 2 status.

As per national guidelines these patient and disease specific characteristics indicate whether new (expensive) medication will be administered. These characteristics therefore have a large effect on costs of care[22].

Case mix adjusted values

For each stratum, the expected RO is the average RO of that stratum over all quarters. For each quarter, the expected RO is the weighted average of the stratum-specific expected RO values in that quarter. The observed RO per quarter is the average observed RO of all the patients in that quarter. The average observed RO is the average RO over all the quarters. Therefore case-mix adjusted RO values are calculated as follows [23]:

Adjusted RO = average observed RO * (observed RO / expected RO)

The average total costs are calculated as follows:

Adjusted Average Total Costs = average observed Average Total Costs * (observed Total Costs / expected Average Total Costs)

Missing data

Missing indicator data could indicate an increased likelihood of failing or succeeding the indicator. With this in mind, we couldn't estimate TO for patients with missing indicator data. Therefore all patients missing one or more clinical indicators were excluded from all analysis.

Supplementary analysis

Because extreme cost outliers may influence QCI values, results were calculated with and without outliers. The cut-off value was selected at P95.

Statistical Testing

The Kruskal-Wallis test with an alpha value of 0.05 (two-sided) was used to determine whether costs were significantly different across outcome categories within populations.

Patient and public involvement

As previously mentioned, patients were involved in the development of the outcome measures via flow tables. Patients were not involved in the design or conduct of this registry based study.

Results

Patient population

Bariatric population

In total, 1172 patients had bariatric surgery between 2019-2020. Due to missing clinical data, 316 patients (27%) were excluded. Of the 856 remaining patients, 639 had a BMI lower than 45 at the start of the treatment (Table 2). Regarding the Bariatric HRQoL population, 270 patients were included of which 203 were diagnosed with a BMI lower than 45 at the start of the treatment.

Breast cancer population

In 2019-2020, a total of 671 patients underwent breast cancer surgery. Eight patients had cancer stage IV at the start of the treatment and were excluded. Of the remaining 663 patients, 208 received a mastectomy and 455 received a lumpectomy.

Bariatric (n=856)*			
Age, median (interquartile range)		46y (34 – 53)y	
Diagnosis	Morbid obesity BMI < 45	639	75%
	Morbid obesity BMI >= 45	217	25%
Gender	M	177	21%
	F	679	79%
Surgery type	Bypass	422	49%
	Sleeve	434	51%
Bariatric including HRQoL (n=270)			
Age, median (interquartile range)		46y (34y -52,75y)	
BMI	Morbid obesity BMI < 45	203	75%
	Morbid obesity BMI >= 45	67	25%
Gender	M	57	21%
	F	213	79%
Surgery type	Bypass	136	50%
	Sleeve	134	50%
Breast Cancer (n=663)			
Age, median (interquartile range)		63y (52y – 72y)	
Cancer stage	0	102	15%
	I	280	42%
	II	236	36%
	III	45	7%
Estrogen receptor status	Pos	406	61%
	Neg	87	13%
	Unknown	170	26%
human epidermal growth factor receptor 2 status	Pos	56	8%
	Neg	437	66%
	Unknown	170	26%
Surgery type	Mastectomy	208	31%
	Lumpectomy	455	69%
neoadjuvant chemotherapy	Yes	122	18%
	No	541	82%
adjuvant chemotherapy	Yes	148	22%
	No	515	78%

Table 2: Characteristics of the breast cancer population and bariatric population with and without HRQoL (number of patients en percentages of total)

** No large imbalances between patients having and not having missing data for all baseline variables except age were found. Lower age was significantly associated with the likelihood of having missing data (p = 0.02).*

Outcome indicators over time

Table 3 describes the crude percentages of patients achieving the health outcome indicator and resulting outcome per year quarter and in total within the different populations.

Population	Outcome indicator	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Total
Baratric care (n=856)	Re-operation	105/2	129/2	90/2	130/3	85/4	54/0	171/2	77/0	**841/15**
		98%	98%	98%	98%	96%	100%	99%	100%	***98%***
	Deficiency	83/24	96/34	64/28	89/44	59/30	39/15	127/45	61/16	**618/236**
		78%	74%	70%	67%	66%	72%	74%	79%	**72%**
	Re-admission	105/2	129/2	90/2	128/5	88/1	54/0	167/6	76/1	**837/19**
		98%	98%	98%	96%	99%	100%	97%	99%	**98%**
	Admission time	102/5	125/6	87/5	130/3	86/3	52/2	162/11	74/3	**818/38**
		95%	95%	95%	98%	97%	96%	94%	96%	**96%**
	ER visit	101/6	121/10	88/4	122/11	81/8	52/2	160/13	74/3	**799/57**
		94%	92%	96%	92%	91%	96%	92%	96%	**93%**
	TWL (total weight loss)	104/3	123/8	80/12	122/11	84/5	52/2	165/7	77/0	**807/48**
		97%	94%	87%	92%	94%	96%	96%	100%	**94%**
	Survival	107/0	130/1	92/0	133/0	89/0	54/0	172/1	77/0	**854/2**
		100%	99%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**72/35**	**81/50**	**47/45**	**73/60**	**50/39**	**34/20**	**107/66**	**56/21**	**520/336**
		67%	**62%**	**51%**	**55%**	**56%**	**63%**	**62%**	**73%**	**61%**
Bariatric including HRQoL care (n=270)	Re-operation	41/2	82/0	56/1	86/2	- /-	- /-	- /-	- /-	**265/5**
		95%	100%	98%	98%	-	-	-	-	**98%**
	Deficiency	32/11	64/18	41/16	60/28	- /-	- /-	- /-	- /-	**197/73**
		74%	78%	72%	68%	-	-	-	-	**73%**
	Re-admission	42/1	82/0	55/2	86/2	- /-	- /-	- /-	- /-	**265/5**
		98%	100%	96%	93%	-	-	-	-	**98%**
	Admission time	40/3	81/1	56/1	86/2	- /-	- /-	- /-	- /-	**263/7**
		93%	99%	98%	98%	-	-	-	-	**97%**
	ER visit	42/1	76/6	53/4	82/6	- /-	- /-	- /-	- /-	**253/17**
		98%	93%	93%	93%	-	-	-	-	**94%**
	TWL (total weight loss)	43/0	80/2	52/5	80/8	- /-	- /-	- /-	- /-	**255/15**
		100%	98%	91%	91%	-	-	-	-	**94%**
	HRQoL	42/1	80/2	53/4	82/6	- /-	- /-	- /-	- /-	**257/13**

		98%	98%	93%	93%	-	-	-	-	**95%**
	Survival	43/0	82/0	57/0	88/0	- /-	- /-	- /-	- /-	**270/0**
		100%	100%	100%	100%	-	-	-	-	**100%**
	Resulting outcome * 100%	**29/14**	**56/26**	**31/26**	**48/40**	**- /-**	**- /-**	**- /-**	**- /-**	**164/106**
		67%	**68%**	**54%**	**55%**	**-**	**-**	**-**	**-**	**61%**
Breast cancer care (n=663)	Re-operation	79/3	55/6	77/3	75/6	88/7	86/5	85/3	83/2	**628/35**
		96%	90%	96%	93%	93%	95%	97%	98%	**95%**
	Survival	82/0	60/1	80/0	81/0	94/1	90/1	87/1	85/0	**659/4**
		100%	98%	100%	100%	99%	99%	99%	100%	**99%**
	Surgical margins	75/7	57/4	74/6	74/7	85/10	87/4	76/12	81/4	**609/54**
		91%	93%	93%	91%	89%	96%	86%	95%	**92%**
	Recurrance	82/0	61/0	80/0	81/0	95/0	91/0	87/1	85/0	**662/1**
		100%	100%	100%	100%	100%	100%	99%	100%	**100%**
	Resulting outcome * 100%	**73/9**	**51/10**	**72/8**	**70/11**	**78/17**	**81/10**	**72/16**	**79/6**	**576/87**
		89%	**84%**	**90%**	**86%**	**82%**	**89%**	**82%**	**93%**	**87%**

Table 3: Number (successful / not successful) and percentage of patients achieving the respective Health outcome indicator per year, quarter within the different populations.

Bariatric outcomes

In the bariatric population, all clinical indicators scored above 90% except the deficiency indicator (73%). Resulting outcome was 0.61, (range 0.51- 0.73). For the Bariatric population including HRQoL resulting outcome was 0.61, range(0.54 – 0.68). During the same period, resulting outcome was 0.59 in the bariatric population. The higher resulting outcome values in the Bariatric population including HRQoL were mainly based on a higher percentage of patients achieving the TWL and deficiency indicators.

Breast cancer outcomes

In the breast cancer population resulting outcome was 0.87, range (0.82 - 0.93). The surgical margins indicator was least successful, with 92% of patients achieving it. The recurrence indicator was the most successful.

QCI values

[Insert figure 1 here]

Figure 1. Case mix adjusted Resulting outcome (panel 1A, 1B), ATC (panel 2A, 2B) and QCI values (panel 3A, 3B) over time for both populations.

Figure 1 displays case-mix adjusted resulting outcome (panel 1A, 1B), average total costs (panel 2A, 2B) and QCI values (3A and 3B). Supplementary results comparing RO, ATC and QCI values including and excluding cost outliers are attached in technical supplements 1 (Breast cancer) and 2 (Bariatric population).

Bariatric resulting outcome, average total costs and QCI values

For the bariatric population RO, ATC and QCI values are presented twice, once including the HRQoL indicator and once for the total bariatric population. As presented in panel 1A, RO values of the Bariatric population including HRQoL are higher compared to the total Bariatric population. Because ATC of both groups are similar (Panel 2A), QCI values of the Bariatric population including HRQoL are higher in 2019 Q2 and Q3. Overall, because ATC of the bariatric population has a low variance (SD = €230.42) deviations in QCI values are mostly due to changes in RO values. Excluding outliers had little impact on RO and QCI (supplementary file 1) values for both groups. ATC values were slightly lower (AVG € 8,388.26 instead of €8,833.55) and less variable (a decrease in Inter Quartile Range (IQR) of € 253.31).

Breast cancer resulting outcome, average total costs and QCI values

The results of the breast cancer population show that QCI (panel 3B) values can be impacted by a combination of both ATC (panel 2B) and RO (panel 1B). For the breast cancer population this is especially true in 2019 Q3 and 2020 Q1. In 2019 Q3 QCI values were highest due to a combination of low costs and high RO values. The opposite is true for 2020 Q3 were a combination of high ATC and low RO values resulted in the lowest QCI value. Excluding outliers impacted the ATC of the breast cancer population predominantly in 2020 (supplementary file 2), producing higher average QCI values (8.08 instead of 6.70) in that period.

Costs per population per outcome Category

Table 4 describes the characteristics of the cost distributions per outcome category for each population.

Population	Outcome category	Number of patients	Average Costs	Standard Deviation Costs	Interquartile Range (IQR) of Costs	P Value
Bariatric care	Admission time failed	21	€ 11,854.96	€ 4,535.65	€ 3,465.92	< 0.01
	Deficiency failed	192	€ 8,452.58	€ 1,457.45	€ 1,603.95	
	ER visit failed	25	€ 8,867.37	€ 1,778.55	€ 1,697.46	
	Other failed	66	€ 12,871.99	€ 10,290.17	€ 3,915.20	
	Textbook outcome	520	€ 8,470.70	€ 1,450.37	€ 1,599.11	
	TWL failed	32	€ 8,603.64	€ 1,448.56	€ 1,685.98	
Bariatric care including HRQoL	HRQoL Failed	6	€ 9,267.24	€ 3,587.81	€ 1,754.82	0.02
	Deficiency failed	54	€ 8,404.37	€ 1,173.08	€ 1,236.08	
	ER visit failed	7	€ 8,661.00	€ 888.35	€ 1,192.50	
	Other failed	30	€ 12,189.78	€ 1,0887.56	€ 2,235.78	
	Textbook outcome	164	€ 8,483.20	€ 1,263.51	€ 1,536.37	
	TWL failed	9	€ 8,165.08	€ 1,029.86	€ 1,733.97	
Breast cancer care	Other failed	11	€ 18,231.83	€ 8,878.90	€ 12,516.42	< 0.01
	Positive Margins failed	47	€ 14,772.80	€ 10,234.77	€ 7,093.75	
	Reoperation failed	29	€ 18,792.08	€ 12,317.22	€ 10,084.12	

	Textbook outcome	576	€ 12,277.29	€ 10,273.12	€ 6,666.06	

Table 4: Descriptive measures of the total costs per outcome category for each population. P values refer to the overall difference in total costs across outcome categories within populations.

Costs of care per outcome category for the bariatric population

For the bariatric population, patients in the Other failed and Admission time failed categories had high average costs of care, compared to the other categories. The Other failed category also had the highest standard deviation and IQR. For the bariatric population including HRQoL, patients in the Other failed category had the highest average costs of care whereas patients in the TWL failed category had the lowest average costs. Total costs by outcome category differed significantly for both populations.

Costs of care per outcome category for breast cancer population

For breast cancer patients, the average costs of the Reoperation failed and Other failed outcome categories were comparable. Patients in the Textbook outcome category had the lowest average costs of care. Again total costs by outcome category differed significantly.

Discussion

In this proof of concept study, we developed the QCI model in collaboration with physicians, patient representatives and healthcare managers based on VBHC principles. The QCI model suits the need for monitoring healthcare costs and health outcomes, and thereby the evaluation and quality assessment of healthcare interventions or quality improvements on an institutional level. The framework provides management information on (patient perceived) health outcomes and costs in a single metric and underlying components, for clinicians and healthcare management.

The results show that the QCI framework is sensitive to changes in average total costs and resulting outcome. A strength of the QCI framework is that routinely collected cost and outcome data from EMR and PROMs software are directly available for QCI analysis. Furthermore, the QCI framework has a high level of flexibility because health gains can be based on a large variety of outcomes, preferably those outcomes that cover all main health effects associated with the care path. This flexibility in outcomes also makes the QCI framework applicable for a variety of medical conditions. These findings indicate that the framework is suitable for monitoring performance of care in terms of outcomes and costs in clinical practice, on an institutional level. Using the framework in a plan do act check cycle, with or without using the underlying indicator and cost data, should help evaluate results and guide continued improvement processes [24].

Not all outcome categories equally affected hospital based costs of care. Failure of outcome indicators with regard to surgery were associated with higher costs. These results can be explained by the direct impact of surgical procedures on hospital based costs [25]. However no direct impact of the deficiency and TWL indicators on hospital based costs of care was visible. On the other hand, deficiencies can lead to the development of metabolic bone diseases in the long-term [26] and obesity is a known risk for coronary heart disease [27]. The follow-up period of one year might not have been sufficient to investigate the expected increase in cost due to these complications. Investing in adherence to follow up could result in a higher percentage of patients passing the TWL and deficiency indicators thereby possibly preventing these long-term costs [28]. Investing in adherence to follow up could therefore, in short term QCI analysis, lead to higher costs and a higher resulting outcome. This indicates that short term QCI values can either improve or decrease depending on whether the gain in resulting outcome outweighs the gain in costs. In a long term QCI analysis, QCI values could improve as additional costs to treat the aforementioned complications could be avoided and resulting outcome increases. Different follow-up periods could therefore result in different QCI values.

VBHC, CEA and QCI all agree that decision making in healthcare should be based on a trade-off between health outcomes and healthcare costs using a outcomes / costs ratio [9]. However both VBHC and CEA require complex calculations to summarize outcomes [7, 9,15,16, 17]. In contrast, in QCI the resulting outcome parameter is an understandable statistic summarizing outcomes. Also, in the basis, VBHC and CEA include social as well as direct healthcare costs. QCI, in this analysis, is limited to costs incurred at the healthcare provider. This matches the clinician and managerial perspective. Alternatively, the model could also include out-of-hospital and non-medical costs if this is relevant for hospital management. Finally, both CEA and VBHC recommend analysis of the full cycle of care. In QCI different follow-up period are available.Short-run or medium term analysis can provide valuable information for managerial purposes.

The definition of textbook outcome as “all clinical outcome indicators are met” gives healthcare providers a pragmatic method to summarize outcomes. However a limitation of this binary scoring model is that value is only created when all health indicators are met (1), and no value is created when at least one of the indicators is failed (0). In the first case, when all indicators are passed, the patient can still perceive the treatment as less then optimal. In the latter case, the patient can view the treatment (at least partially) as a success. The binary scoring rule could therefore result in an overestimation of value, but is more likely to lead to an underestimation of value. An alternative approach could be to define an outcome measure with a continuous score that varies between completely suboptimal outcome (0) and completely optimal outcome (100), with or without assigning different weights to different outcome indicators. Another limitation is missing data. When data from one indicator is missing and the other indicators are passed, QCI values are not defined. Because the QCI framework can give an under- as well over-estimation (or no estimation in the case of missing data) of value on the micro level(physician-patient encounter) [6], the framework isn’t applicable at this level. The QCI

model can give valuable information on an institutional level as it summarizes group outcomes and costs in an understandable fashion.

Areas of future research include defining upper and lower margins for outcome, costs and QCI values to guide continued improvement processes. Because as time passes chances of failing or succeeding an indicator can vary [29], future research should investigate resulting outcome and textbook outcome values over multiple follow-up periods. Comparing hospital performance using the QCI framework could be helpful for optimizing QCI values and underlying costs and outcome results [30]. Finally, the QCI framework should be applied to more medical conditions, in chronic and acute settings to study the generalizability of the properties of the QCI model.

Conclusions

This proof of concept study showed that the QCI framework is effective for monitoring the performance of care paths in terms of costs and health outcomes on an institutional level. An overall impact of health outcome indicators on hospital based costs of care is found. Also, some indicators, or combination of indicators, impact costs more than others.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval statements that refer to your institution

Because the study retrospectively evaluated care as usual a Medical research Ethics Committee review isn't obliged under Dutch Legislation. The Institutional Review Board of the Franciscus Gasthuis & Vlietland hospital, named Advies Commissie Wetenschap (ACW) reviewed and waived the study protocol (ref. 2023-002). The ACW stated that retrospective collection of informed consent was not required for this registry-based study. The effort to do so would be disproportionate due to the number of patients in the study and the fact that the treatment occurred some time ago. The study was conducted in accordance with the Declaration of Helsinki.

Contributorship statement

The study was conceived by WHP and JB. Data collection, analysis were performed by WHP. The manuscript was drafted by WHP and EB. Methodological and statistical integrity was checked by EB. SD, TMALK, and AEAMvW provided feedback on the manuscript. All authors read and approved the final manuscript.

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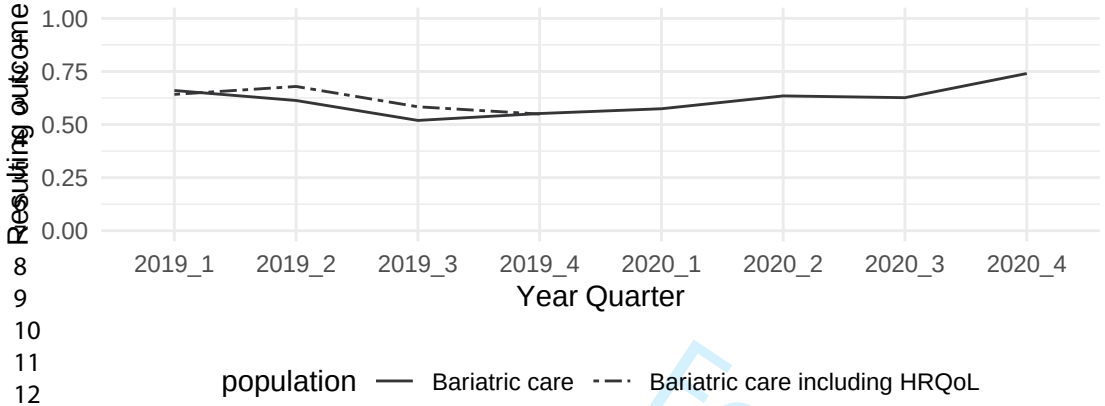
Availability of data and materials

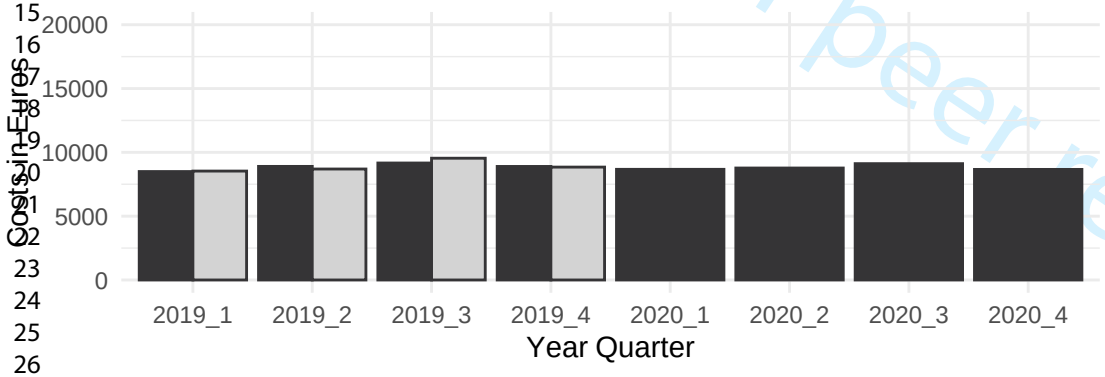
The datasets used in this study are not publicly available under the Dutch privacy legislation. Anonymized datasets can be made available from the corresponding author on reasonable request

Bariatric population

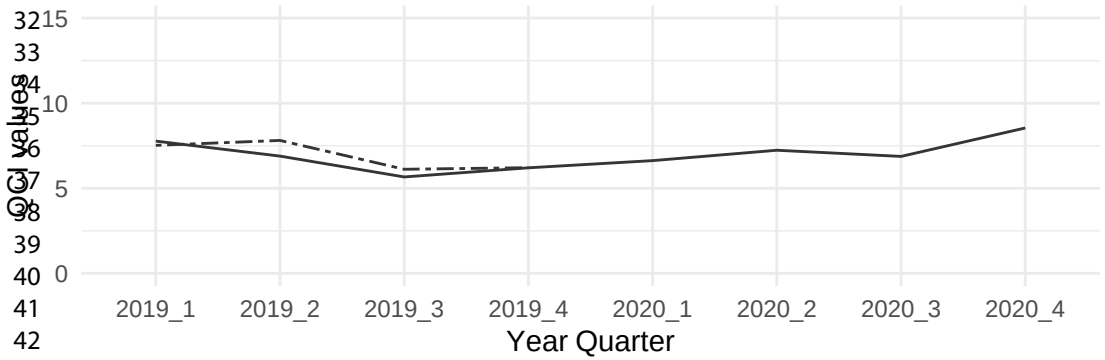
1A: Resulting outcome per Year Quarter

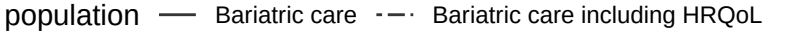


2A: Average total Costs per Year Quarter



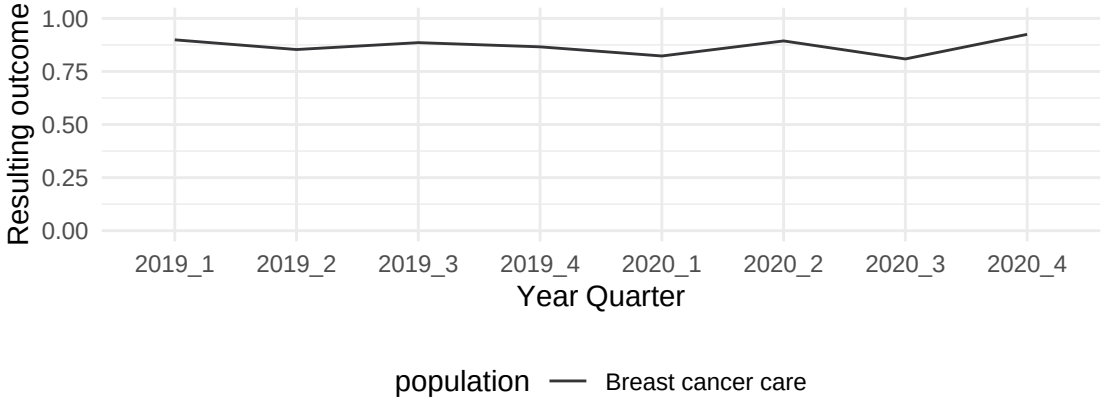
3A: QCI values per Year Quarter



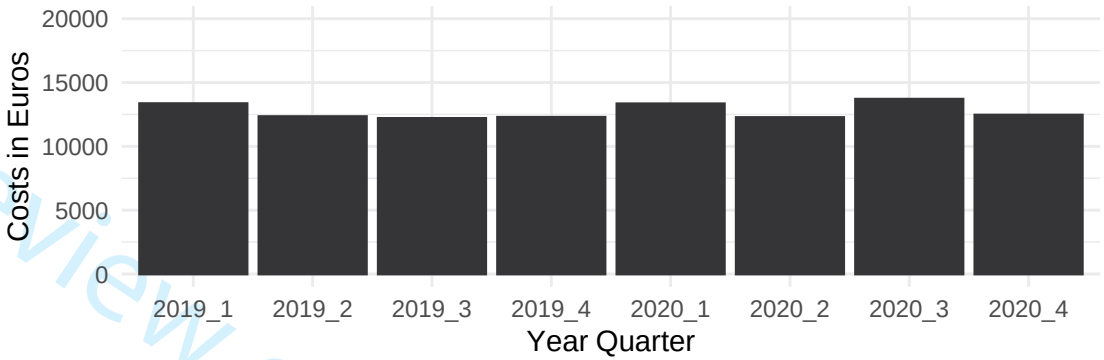


Breast cancer population

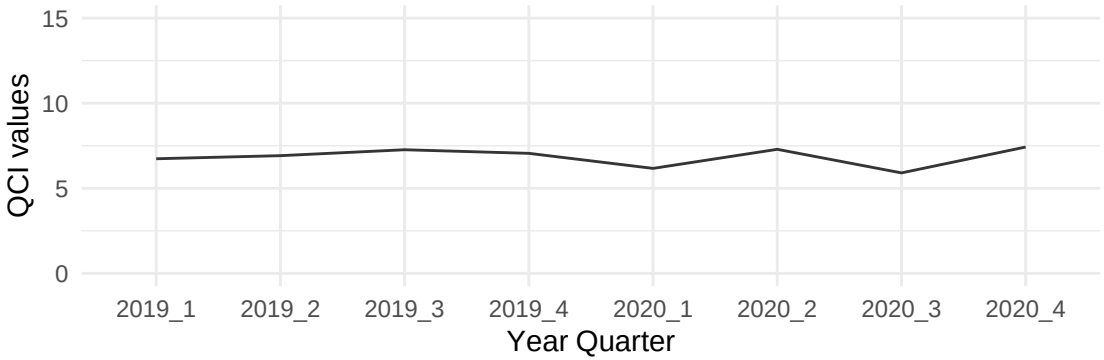
1B: Resulting outcome per Year Quarter

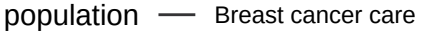


2B: Average total Costs per Year Quarter



3B: QCI values per Year Quarter





Appendix 1: Health outcome indicators

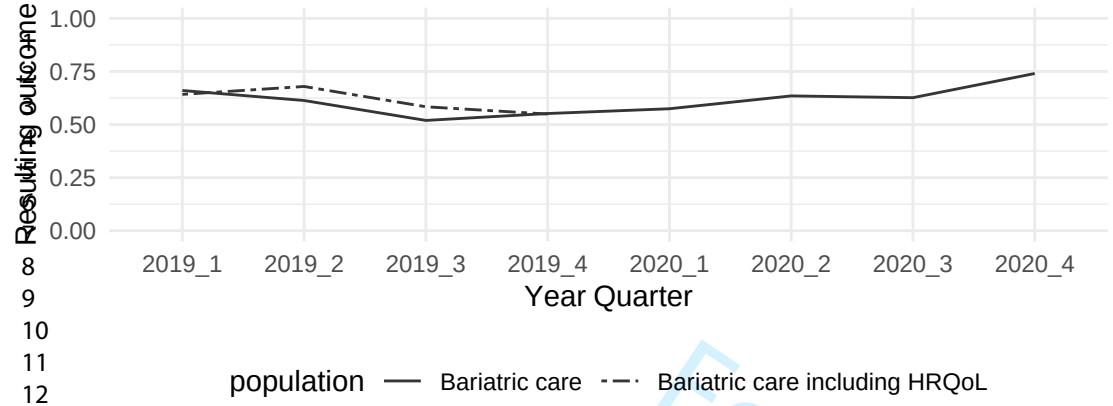
Patient population	KPI	Description	Success measure
Bariatric	Re-operation	The following surgeries within 30 days of the primary surgery were taken into account: - Operative treatment for esophageal perforation - Endoscopic extension gastric bypass - Endoscopic sleeve and Pouch bypass - Endoscopic gastronomy - Overstitching stomach perforation (open/ endoscopic) - Endoscopic small intestine resection - Endoscopic intestinal anastomosis - Overstitching intestinal perforation (open / laparoscopic) - Cholecystectomy laparoscopic - Laparotomy - Closure of the Petersen mesenteric defect - Bleeding within 24 hours of the primary surgery - Incisional hernia (open / laparoscopic)	If a surgery was performed within 30 days following the primary surgery, the treatment failed to meet the clinical outcome indicator.
	Deficiency	The following blood levels were measured: - Ferritine (22 µg/L) - Active B12 (32 pmol/L) - Folate (7 nmol/L) - Vitamin B1 (70 nmol/L) - Vitamin B6 (35 nmol/L) - Vitamin D (50 nmol/L)	The blood level measure after 9 months and before 21 months closed to one year mark post-surgery was used as the measure to decide if the patient had deficiencies. If in this measure any of the blood levels were below the norm levels the patient was classified as deficient and therefore failed the clinical outcome indicator.
	Re-admission	Hospital admissions within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation	If there was an additional unplanned admission the treatment was stated to have failed to meet the clinical outcome indicator.

		- Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	
	Admission time	Admission time directly following the surgery	If admission time of the primary admission exceeded 72 hours treatment was stated to have failed to meet the clinical outcome indicator.
	ED	Emergency deparment visits within 30 days post-surgery having one of the following diagnoses: - Acute abdomen (peritonitis) - Hernia diaphragmatic - Incisional hernia - Pyloric hypertrophy - Pylorospasm - Gastroesophageal Reflux - Other (stomach) complaints - Local skin and subcutis infections - Abcess intra-abdominal - Morbid obesity (BMI <45) - Morbid obesity (BMI >45) - Duodenal ulcer / ventricles + perf - Obstipation - Cholecystitis / Cholelithiasis - Pancreatis - intussusception - mesenteric thrombosis - Volvulus bowel - Ileus - Other non-maligant Gastrointestinal condition - Acute deep venous pathology	If there was an emergency department visit within 30 post surgery the treatment failed to meet the clinical outcome indicator.
	TWL (total weight loss)	(Initial weight – current weight) / initial weight	If TWL exceeded 20% in a period of 455 days following the surgery the clinical outcome indicator was considered successfully passed.

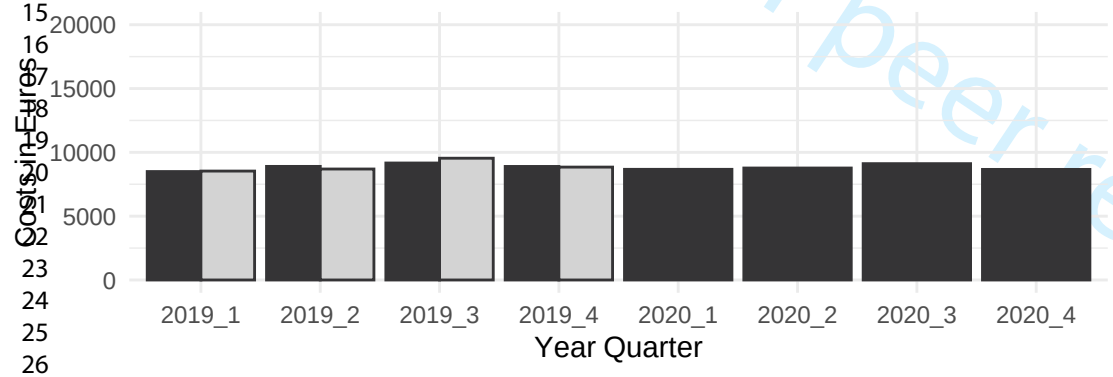
Breast Cancer	Re-operation	All surgeries due to infections or bleeding as a result of the primary surgery:	Once a patient received a surgery due to infections or bleeding the treatment was stated to have failed to meet the clinical outcome indicator.
	Surgical Margins	All patients who received surgery (lumpectomy or mastectomy) due to close or positive margins	Once a patient did receive surgery the treatment the treatment was stated to have failed to meet the clinical outcome indicator. If margins did not need a further surgery the clinical outcome indicator was considered to be successfully passed.
	Recurrence	All who had a recurrence of the primary tumor. It was considered all these patients did receive surgery (either an mastectomy or mastectomy).	Once the patient received surgery to treat the recurrence the treatment the treatment was stated to have failed to meet the clinical outcome indicator.

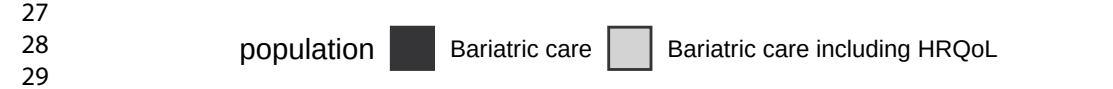
Bariatric population

1A: Resulting outcome per Year Quarter

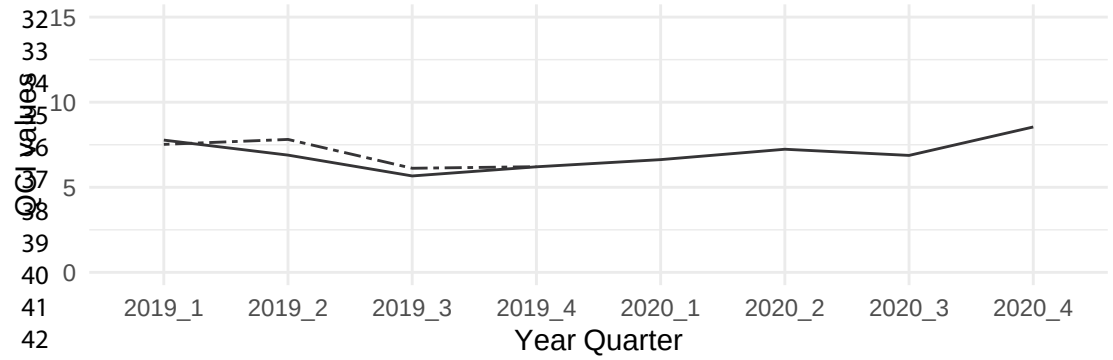


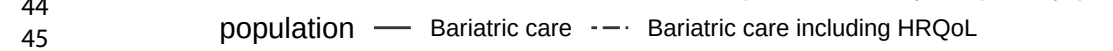
2A: Average total Costs per Year Quarter





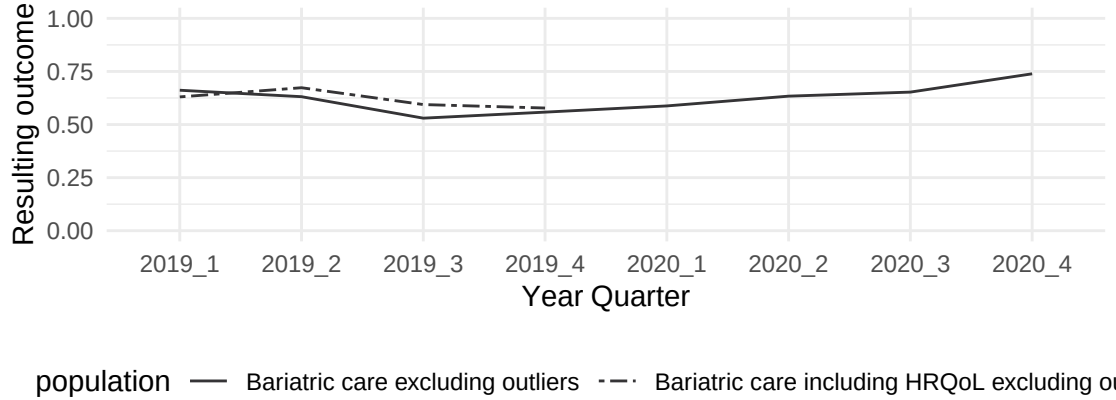
3A: QCI values per Year Quarter



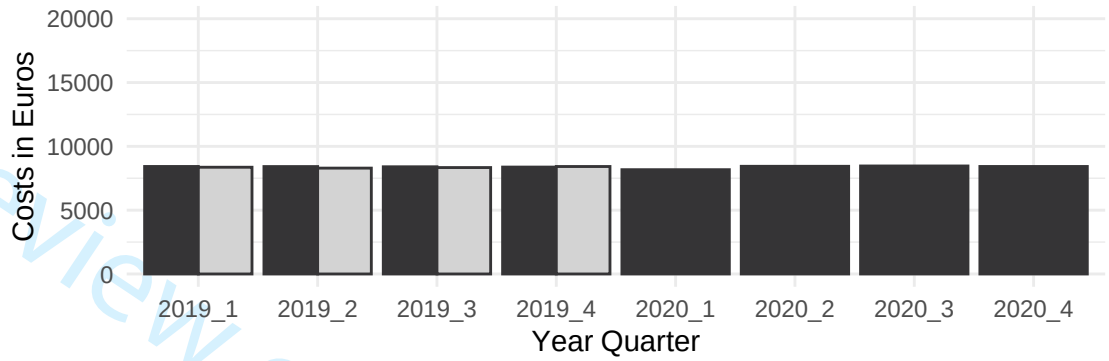


Bariatric population excluding outliers

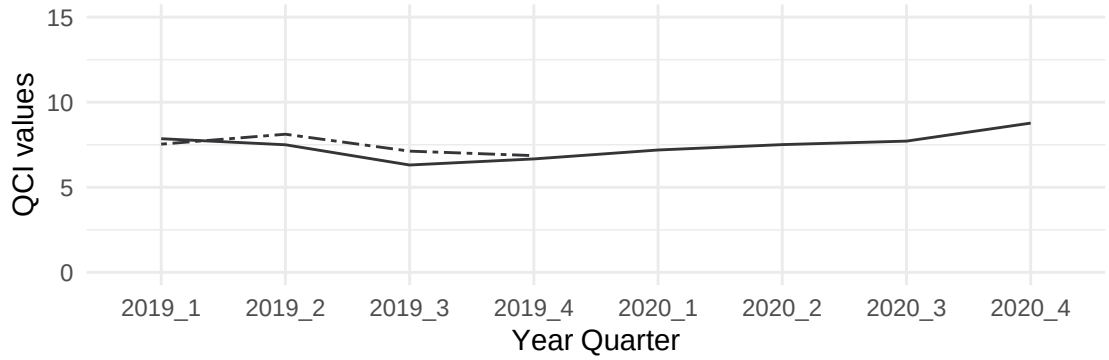
1A: Resulting outcome per Year Quarter

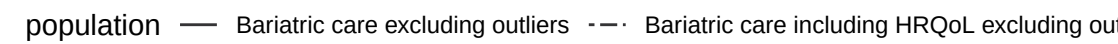


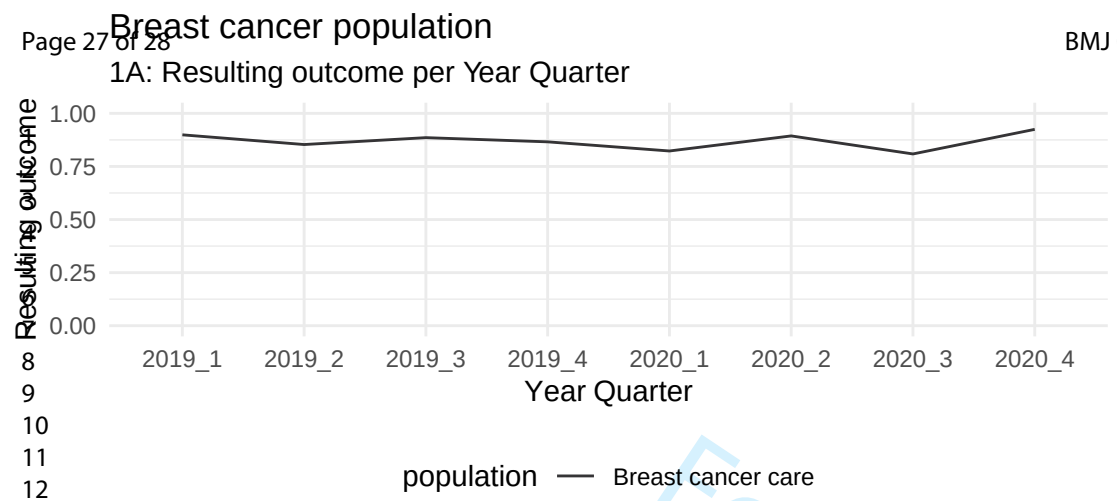
2A: Average total Costs per Year Quarter

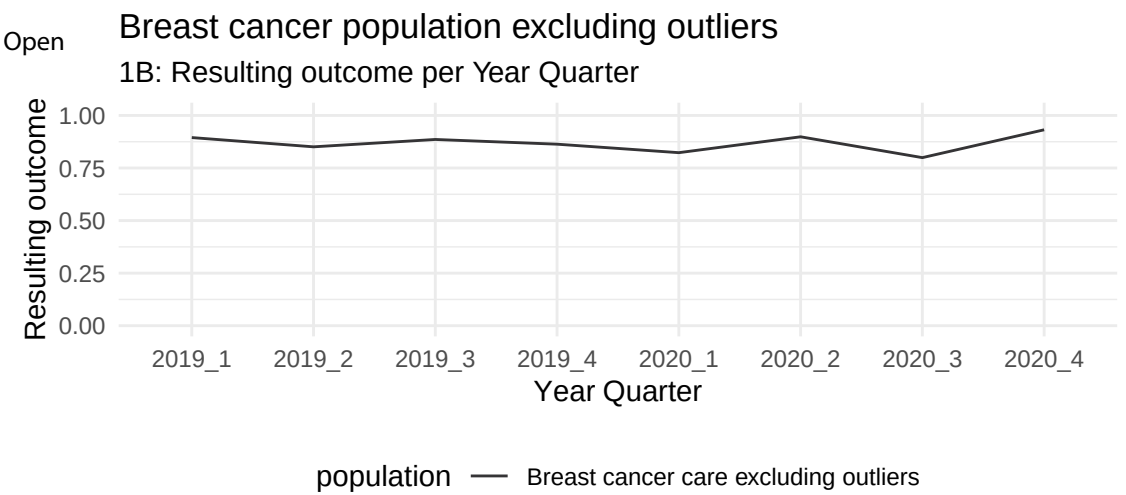


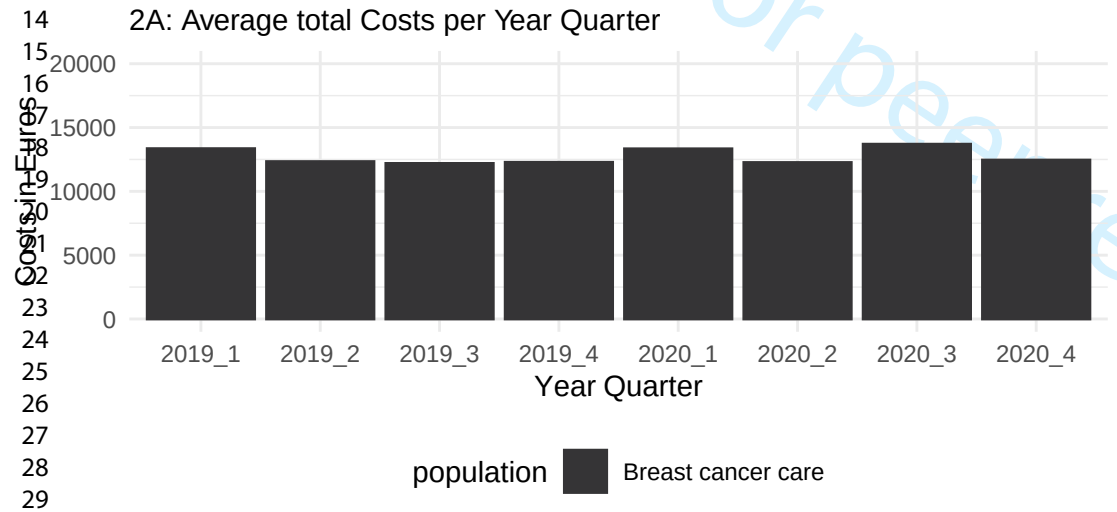
3A: QCI values per Year Quarter

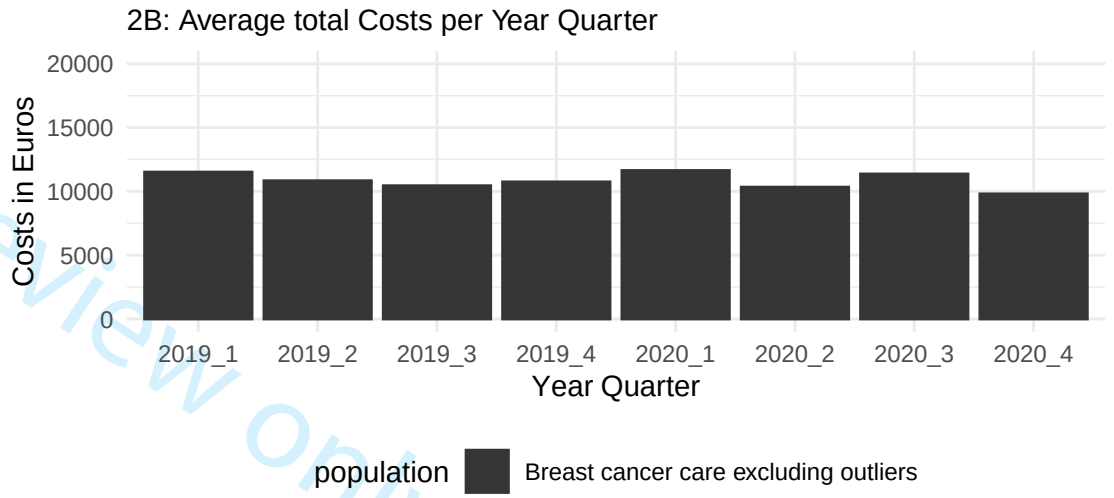


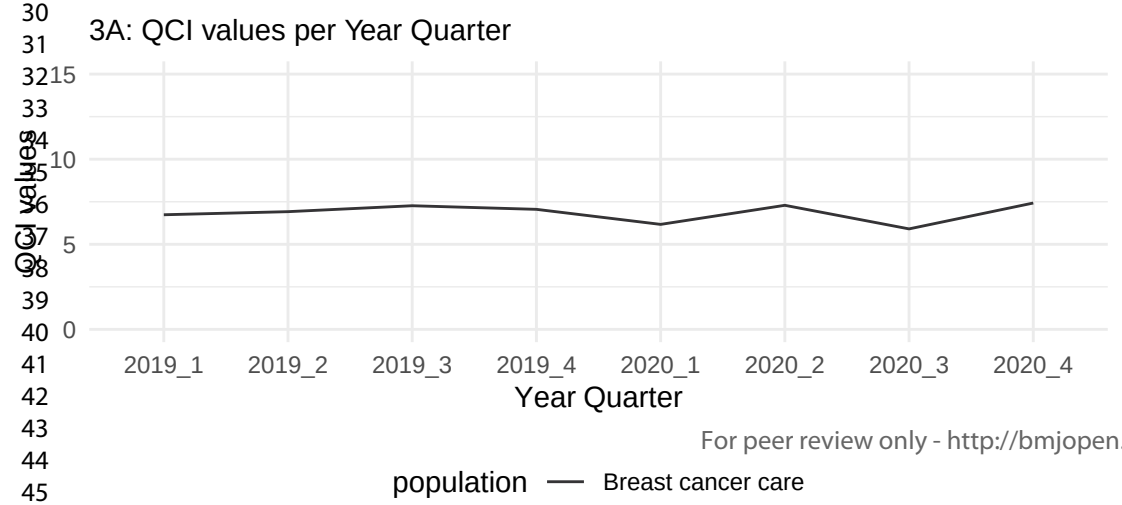


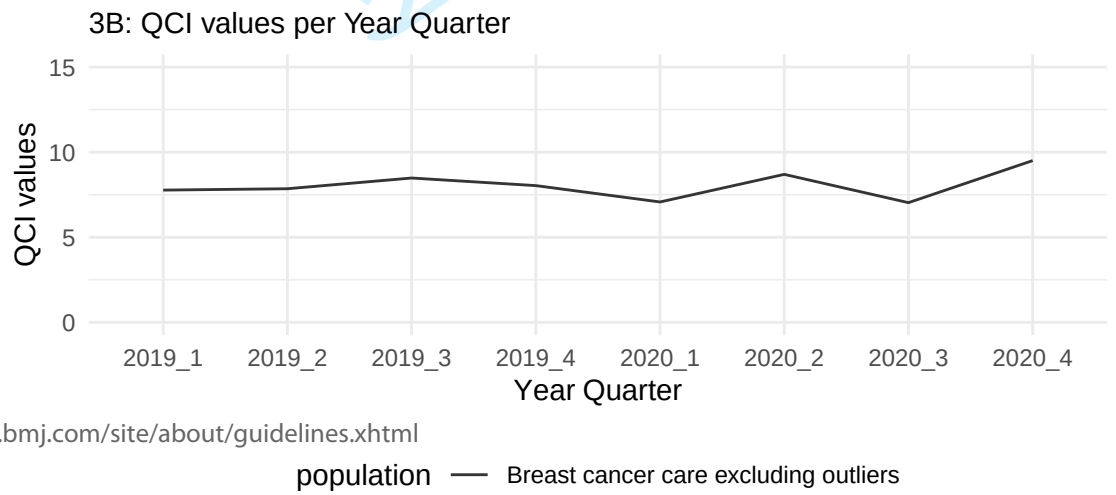












STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title page
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4&6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4&5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5&6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6&7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	10 up to 13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	13
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.