Effects on health and costs of delayed implementation of the ^{EE93} Oncotype DX[®] test for eligible breast cancer patients in Sweden.

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Summary findings

- Delayed implementation of the Oncotype DX Breast Recurrence Score test will result in reduced financial savings and a decline in quality-adjusted life years (QALYs).
- Cost-effectiveness estimates indicate that the Oncotype DX test leads to superior cancer outcomes at lower costs (dominant strategy) relative to no GEP and naive compared to Prosigna.

3 Method

A cost-effectiveness analysis (CEA) was conducted using a decision-analytic model to evaluate the cost-effectiveness and EVPIM of gene expression tests. The CEA compared three strategies: no gene expression profiling (GEP), the Prosigna test, and the Oncotype DX test. Notably, available data does not permit direct comparison between the Prosigna and Oncotype DX test.

1) Background

The ten-year breast cancer survival rate exceeds 80%, yet improvement is possible (1). Genomic data enhances chemotherapy selection in breast cancer (2). In Sweden, the Prosigna and Oncotype DX tests are available but underutilized in clinical practice.

4 Results

Table 1. Base-case cost-effectiveness results for theOncotype DX test compared to no GEP and theProsigna test for N0 & N1 patients.

				Diff	Diff
Result for	Oncotype			(Oncotype DX	(Oncotype Dx
N0	DX	Prosigna	No GEP	vs Prosigna)	vs No GEP)
Total costs (SEK)	705 286	742 232	716 953	-36 945	-11 667
Total QALYs	12,17	12,04	12,03	0,134	0,139
Total LYs	15,18	15,03	15,02	0,148	0,154
				Diff	Diff
Result for	Oncotype			(Oncotype DX	(Oncotype Dx
N1	DX	Prosigna	No GEP	vs Prosigna)	vs No GEP)
Total costs (SEK)	751 749	1 002 542	761 342	-250 793	-9 593
Total QALYs	12,05	11,28	12,01	0,769	0,034
Total LYs	15,04	14,19	15,02	0,847	0,019

2 Aim

This study examines the cost-effectiveness of gene expression tests in early-stage breast cancer patients by comparing Oncotype DX test with the Prosigna test or no gene expression profiling (GEP). Additionally, the expected value of perfect implementation (EVPIM) of these tests was assessed (3).

Table 2. The EVPIM for Oncotype DX vs No GEP in different Swedish regions for NO and N1. For early breast cancer NO and N1. Result presented as costs, QALYs, LYs, net monetary benefit (NMB), and net health benefit (NHB).

Regions	Cost	QALY	LYs	NMB	NHB
Stockholm	-11 312 899	116	124	92 973 474	132
Uppsala	-1 921 169	20	21	15 788 861	22
Södermanland	-1 674 004	17	18	13 757 567	20
Östergötland	-2 432 171	25	27	19 988 458	28
Jönköping	-1 883 948	19	21	15 482 966	22
Kronobergs	-1 032 885	11	11	8 488 622	12
Kalmar	-1 450 421	15	16	11 920 083	17
Gotland	-382 319	4	4	3 142 032	4
Blekinge län	-896 960	9	10	7 371 539	11
Skåne län	-7 062 197	73	78	58 039 671	83
Halland	-1 846 084	19	20	15 171 784	22
Västra Götaland	-8 933 058	92	98	73 415 082	105
Värmland	-1 646 139	17	18	13 528 561	19
Örebro	-1 631 012	17	18	13 404 240	19
Västmanland	-1 646 139	17	18	13 528 561	19
Dalarna	-1 695 087	17	19	13 930 832	20
Gävleborg	-1 694 737	17	19	13 927 962	20
Västernorrland	-1 433 842	15	16	11 783 827	17
Jämtland	-752 947	8	8	6 187 990	9
Västerbotten	-1 432 831	15	16	11 775 519	17
Norrbotten	-1 477 735	15	16	12 144 557	17
Nation	-54 238 584	558	596	445 752 187	635

Model parameters were sourced from published literature and adjusted for Swedish (4). The analysis focused on settings postmenopausal women with ER-positive, HER2-negative invasive breast cancer, without distant metastasis. A societal perspective was adopted, encompassing informal care and production loss due to morbidity. The analysis covered a lifetime horizon based on an annual cohort. Result was presented as costs, QALYs, life-years (LYs), net monetary benefit (NMB), and net health benefit (NHB).

Data for the 2023 the study population was obtained from the national quality register for breast cancer (5). Figure 1 outlines the steps to identify the study population. The distribution data for post- and pre-menopausal women, as well as node-negative (N0) and 1-3 lymph node metastases (N1) cases, were derived from existing literature (6). The economic analysis demonstrates superior cost-effectiveness of the Oncotype DX test, yielding higher QALYs and substantial savings. Specifically, Oncotype DX test implementation in Sweden could annually enhance QALYs by 558 to 1,365 and LYs by 596 to 1,505, with cost savings ranging from 54 to 419 million SEK compared to no GEP and Prosigna respectively (Table 3). These results underscore the potential benefits of widespread Oncotype DX test adoption in clinical settings.

Figure 2. Cumulative net cost after implementation of the Oncotype DX test vs no GEP, for N0 and N1. The implementation becomes cost-saving after 7 years.



Table 3. The EVPIM result for the Oncotype DX test in comparison with no GEP. And naive comparison with the Prosigna test. For early breast cancer NO and N1.

Result for N0 & N1	Oncotype DX vs No GEP
Total QALYs	+558
Total LYs	+596
Total costs (SEK)	-54 238 584
Results for N0 & N1	Oncotype DX vs Prosigna
Results for N0 & N1 Total QALYs	Oncotype DX vs Prosigna +1 365
Results for NO & N1 Total QALYs Total LYs	Oncotype DX vs Prosigna +1 365 +1 505

5 Conclusions

The findings support the swift adoption of the Oncotype DX test in Swedish clinical practice due to its superior cost-effectiveness and potential to improve patient outcomes. Full implementation could significantly increase QALYs and LYs while offering substantial

Figure 1. Flow chart of study population.



Figure 3. Cumulative net cost after implementation of the Oncotype DX test vs the Prosigna test. Estimation is for both N0 and N1. The implementation of the Oncotype DX test is cost-saving.



financial savings. Thus, prioritizing the Oncotype DX test is crucial for maximizing its clinical and economic benefits for breast cancer treatment in Sweden.

References

1. Regionala cancercentrum i samverkan. National breast cancer care program. Regionala cancercentrum i samverkan. 2024;version 5,0.

2.The Dental and Pharmaceutical Benefits Agency (TLV). Gene expression tests, Sweden. 2021.

3. Fenwick E, Claxton K, Sculpher M. The value of implementation and the value of information: combined and uneven development. Med Decis Making. 2008;28(1):21-32.

4.The Dental and Pharmaceutical Benefits Agency (TLV). Health economics analysis of Oncotype DX Breast Recurrence Score test. 2021.

5. Nationellt kvalitetsregister för bröstcancer [Internet]. 2024 [cited 2024-05-20]. Available from: <u>https://statistik.incanet.se/brostcancer/</u>.

6.Narbe U, Bendahl PO, Fernö M, Ingvar C, Dihge L, Rydén L. St Gallen 2019 guidelines understage the axilla in lobular breast cancer: a population-based study. Br J Surg. 2021;108(12):1465-73.



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