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RESEARCH

# Supporting breast cancer decisions using formalized guidelines and experts decision patterns: initial prototype and evaluation

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**Abstract**

Transparent decisions and its documentation of breast cancer patients' therapy are getting more important especially since modern therapeutic approaches favor personalized forms of treatment. The medical decisions for a treatment are very complex, because there are rules and different options for each patient. To support the decision process, we analyzed the current decision rules and implemented them in a prototype of a rule-based expert system. Thus, this system shall support the quality assurance regarding transparent documentation of individualized therapeutic decisions. For evaluating the system, we used data from a state tumor center and compared the decisions suggested by our system with expert ones. The system and the expert approach will be compared with each other as well as the differences in the treatment decisions. The first preliminary results show us that the human factor—like must be considered by creating a decision support system. The prototype delivers first results, which are restricted, but the results are promising for further developments.

**Keywords:** Breast cancer treatment, Decision support, Tumor board

## Introduction and background

Breast cancer is the most common cancer in women, accountable for more than 17,000 annual deaths. In 2014, approximately 75,000 additional cases of corresponding tumors were diagnosed, only in Germany [1]. It goes without saying that deciding on treatment alternatives does represent one of the more vital decisions in healthcare since potentially impacting patients' life in a dramatic way. Those decisions are usually made during so-called tumor conferences (also known as tumor boards) organized by the breast cancer centers or, in short, breast centers attended. Alone in German-speaking parts of Europe including Austria, Switzerland and Southern Tyrolian, there are more than 280 of these breast centers listed by and certified along the requirements of OnkoZert Institute.[1] Another 25 institutions, mainly in Belgium, Switzerland and a dozen from Italy have been certified by the European Society of Breast Cancer Specialists—EUSOMA.[2]

Since the advent of modern, personalized therapeutic approaches [2], a transparent documentation of therapeutic decisions is getting mandatory in more and more

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[1] Cp. http://www.senologie.org/brustzentren/zertifizierung-von-brustzentren-fragen-und-antworten-faq/?L=registration.register/; retrieved 2016-07-08.

[2] Cp. http://www.breastcentrescertification.com/breastcentrescert.php; retrieved 2016-07-08.

fields. Since for most quality management certifications consistent documentation is needed, certification provider OnkoZert requires breast centers to transparently document recommendations of the tumor conference for the patient (e.g., item 1.6.5 as of audit requirements per [3]). In industrial environments, such representation of decisions is achieved by process and decision diagrams (e.g., decision trees) [4–6].

In contrast to this, treatment recommendations as the basis for individual therapeutic decisions are represented as statements in a variety of guidelines in medicine in general as well as in defined diseases like breast cancer: e.g., the GoR III/S3-Guideline on "Diagnosis, Treatment and Aftercare of Breast Cancer" [7], cp. Section 3. They can also emerge as summarized results of large international consensus meetings like the St. Gallen Meeting (International Breast Cancer Conference—Primary Therapy of Early Breast Cancer Evidence, Controversies, Consensus). Thus, in order to provide the best available therapy, the attending experts' decisions are based on the best available external evidence combined with the physicians' knowledge and, of course, their professional experience or even other factors like patient- and tumor-related issues or professional preferences or attitudes [1, 24].

Conformity of the treatment with the recommendations of guidelines has a significant impact on the patients' survival in breast cancer. Retrospectively, Wöckel et al. analyzed a cohort of 3976 patients of whom only 2063 patients (not even 51.9%) were treated in conformance with the guideline. This cohort was compared to those patients with nonconforming decisions (1913; 48.1%): The latter group had a much worse prognosis according to the deliverables of this study [9]. These results are backed up by Wolters et al. [10].

However, even though both contributions could validate a share of about half of conform treatments, they could not explain what reasons were significant for nonconforming decisions: those were not documented in the patients' records (notwithstanding the open issue why that is). To better understand this situation as a basis for potential improvement, we designed a web-based prototype of a rule-based expert system as a model of the guideline (and—as a goal—eventually of the boards' decision process). The relevant parameters for individual decisions were derived from various sources and were transferred to executable rules, composing the systems knowledge base. Entering a patient's individual and tumor associated data will prompt an individual treatment proposal in the background. This proposal, together with the relevant decision criteria and the de facto decision of the attending physician, if conforming to the system's proposal, are documented in a transparent way. This should support with examining and understanding the decision process and challenges within as well as the documentation of all treatment proposals—whether guideline conform or non-conform. In regard to a consistent documentation, process models may play a key role since process orientation is increasingly adopted in the health industry [11]. Modeling efforts then usually target medical knowledge or decision-making, also from an organizational perspective [12]. Yang et al. even claim that decisions in processes are a major endeavor to corporate knowledge management [13]. From our perspective, we recognize a twofold knowledge management issue, here: 1. The deviation or (alleged) advantage of the physicians' knowledge (and thus decisions) over the guideline, 2. The lack of transparent decision documentation for the patient or another provider. Schlieter and Esswein found out that transparent models of healthcare workflows also help organizations in the industry with quality management and (re-) certification [14]. Spreckelsen et al. predicted that the need of knowledge based systems will increase in the future—the fields of development are very complex (like e.g., decision support, data integration or modeling/process modeling) [30]. We think that workflows and decision support belong together: that is why model-based decision support and documentation are of utmost importance and play a key role here.

## Related work

We describe in this part about the processes and decision rules in breast cancer treatment. Process modeling often goes in general along with design-oriented approaches. This contribution follows the design (science) research paradigm [15] and presents a prototype to be classified as an innovative (IT) artefact targeting the analysis of specific healthcare services. It aims at providing an added value for stakeholders in both research and practice, including patients. To achieve this, we first introduced the relevance of the problem as per recent developments and stated by the research objective.

Design research is suggested for use in healthcare (e.g., by Rouse [16], Görlitz and Rashid [17]) as well as for the use of IT, there (e.g., by Hegde and Raheja [18]). Corresponding approaches have proven effective in the domain for implementing eHealth- [19] or mHealth-services [20], for instance.

Enhancing models is appropriate to leverage decision quality in healthcare [13], eventually towards computer-interpretable guidelines (cp. [5, 26]), or integrating process-aware concepts might further advance this approach towards executable process instances in healthcare (cp. [27]). Information (system) models "will remain always partial", however, they are particularly vital to interact

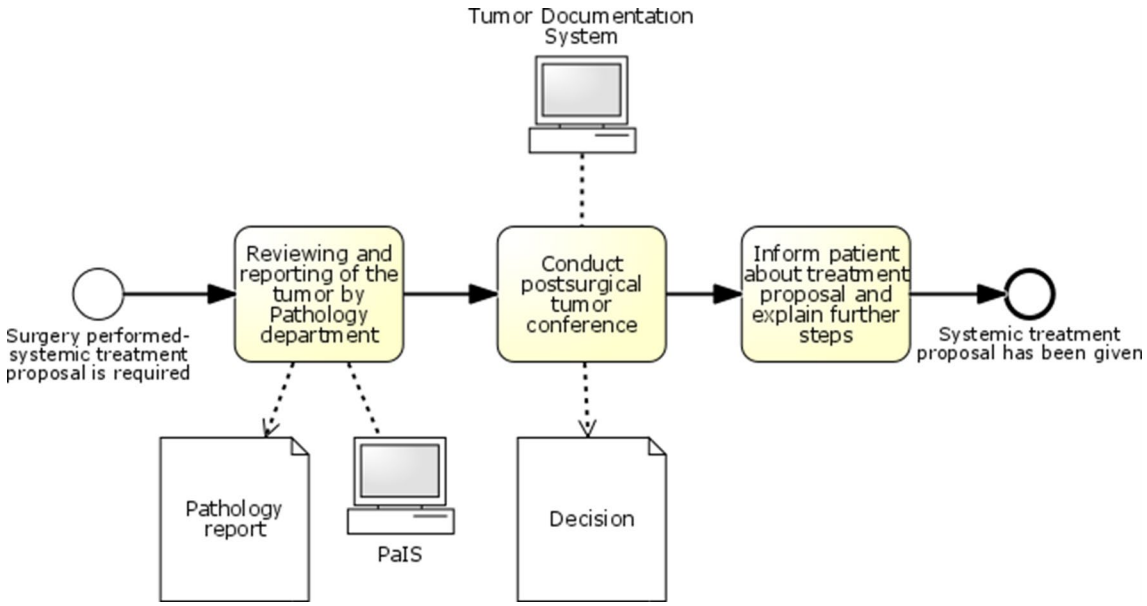


**Fig. 1** Process steps for a treatment proposal within hospital and breast center

**Table 1 Descending with quality (i.e., degree of systematic development)**

| Abbreviated level categorization of guidelines | Description of categorization criteria |
|---|---|
| S3/GoR III | Care guideline based upon both evidence-base and formal consent process of representative committee |
| S2e | Care guideline based upon systematically (review, synthesis) proven evidence-base |
| S2 k | Care guideline based upon formal consent process of representative committee (e.g., Delphi conference) |
| S1 | Care recommendations based upon informal consent of an expert committee |

with stakeholders [12] as for finding decision support solutions, though [28].

Case studies are adequate when there has only been limited knowledge about a topic or where dynamic phenomena are going on [21] and correspond with design-oriented means to combine methods (use cases, experiments, interviews etc.) for analyzing information systems [22]. For evaluating the prototype, we use a dataset of 100 patients' treatments as an experimental case study (here postsurgical treatment decision in breast centers): Wwe are focusing the process after the surgical therapy (our use case) regarding the systematic treatment proposal to check if the prototype matches the decisions as made in tumor boards of the 8 hospitals' breast centers of a federal state (obtained from the state's tumor center) for an aforementioned number of patient cases (our experiment). The data were chosen randomly from the ones available as complete as possible.

The postsurgical process steps for a treatment proposal are shown in Fig. 1 for an overview: the tumor tissue has been sent to the Pathology department and the responsible pathologist reviews it and writes a report using the Pathology Information System. A postsurgical tumor conference will take place to generate a treatment proposal. The board consists of physicians (especially the attending physician—e.g., often a gynecologist, oncologists, radiologists, pathologists, radiotherapists) and their decision for a treatment proposal shall be based on tumor- and patient-related parameters. After the conference, the patient will be informed about the proposal and further steps shall be explained.

An overview of materials and methods used is next. Subsequently, we will present and discuss results. However, besides the processes also rules are important that complement the processes. In previous work, we analyzed the business processes and the business rules of

a state breast center and represented the processes in BPMN and the decision diagrams and tables in DMN to get an overview over the decisions in general. We also analyzed the S3 guideline on "Diagnosis, Treatment and Aftercare of Breast Cancer". We combined the analysis with the knowledge of the processes/decisions and maintained the decision rules in a comprehensive matrix [24]. "Clinical practice guidelines should be based on the best scientific evidence derived from systematic reviews of primary research" [23], cp. Table 1 categorizing the different levels of guidelines' quality with the most systematic, S3, at top.

## On the design of a prototype for breast cancer treatment

We describe in this part the design of a prototype for breast cancer treatment. The rules have been analyzed from expert interviews and from the current version of the S3 guideline. The first part contains processes and rules, the second part describes the application logic and the third part the User interface.

### Processes and rules

The decision parameters and its implementation in the prototype and the user interface of the prototype. We also describe the different parameters to get an easy understanding of the medical terms, which will be used in this and the next part.

In this first step we start with the decision parameters and their implementation in the prototype. The resulting decision rules were checked and amended by means of structured expert interviews. This paper reports on the first preliminary results of our prototype comparing the systems suggestions with the actual decisions of the attending physicians.

To support the optimal and best treatment decision for the individual patient, we developed this prototype based on the specific use case of a tumor conference. The tumor board is a council of medical experts discussing and deciding the best treatment approach. Since the number of the analyzed decision rules was rather small, we decided to implement the analyzed rules from a decision table directly into the source code of the system. This prototype was primarily meant to support and thus improve physicians' documentation of therapy-related decisions. The system, however, generates a treatment proposal in the background for evaluation reasons invisible to the physicians. We were thus able to compare the conformity of the system's proposals with the actual decisions of the attending physicians.

To generate a guideline-conform decision, experts as well as the system need to know all decision relevant parameters. Those are composed of patient-related as well as tumor-related information and background on the recommended treatment:

- Patient-related information: Age, menopausal state and ECOG performance-status.[3]
- Tumor-related information: Tumor size-, Nodal- and Metastasis status according to the TNM staging system[4] as well as the three tumor growth factors: hormone-receptor status, HER2/neu receptor rate and the tumor's grading for cell abnormality. Regarding chemotherapy, additional indicators for growth like the anti-gene protein Ki67 level and the protein uPA/PAI1 level were found to be helpful by some of the experts interviewed and were thus included as non-compulsory items.
- Information on the recommended treatment: Besides the plain information on the type of treatment we added a text field to assemble information about the reasons for the respective choice.

The patient's age is not as such a limiting factor for any kind of treatment recommendation, but in combination with comorbidities and the patients' general condition it could be a surrogate parameter influencing physicians' decisions. Patients' menopausal status is required to decide which kind of endocrine therapy (use of the Tamoxifen versus 3rd generation aromatase inhibitors) will be recommended. To make comorbidities and the patients' general condition a more transparent item, we decided to implement the ECOG performance status. The tumor size, nodal status and metastasis status of the tumor were categorized via the TNM classification, which has been developed by the World Health Organization (WHO). T stands in this case for tumor size and it is generalized into T0, Tis, T1, T2, T3 and T4.[5] N stands for nodes and it is generalized into N0, N1, N2 and N3. M stands for metastases and it is summarized in M0 and M1. The hormone receptor status contains the estrogen and progesterone receptors of the tumor. HER2 is also a protein, which will be tested in the tumor tissue—it can like the hormone receptor state be positive or negative. The grading describes how the cancer cells look under the microscope and is summarized in G1 (low grade), G2

[3] Cp. 9. Eastern Cooperative Oncology Group—ECOG-ACRIN cancer research group, http://ecog-acrin.org/resources/ecog-performance-status; last accessed 2016-07-11.

[4] Cp. 10. International Union Against Cancer – TNM Classification of Malignant Tumors, 7th edition, http://www.uicc.org/resources/tnm; last accessed 2016-07-11.

[5] For further information regarding the tumor staging read more at http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/treatment/tnm-breast-cancer-staging.

(median grade) and G3 (high grade) [29]. The anti-gene protein Ki67 level and the protein uPA/PAI1can have the characteristic low or high—which means that a chemotherapy might be useful or not (if low).

#### Application logic

The prototype consists of the following input fields: ID, age, menopausal status, ECOG status, T-classification, N-classification, hormone receptor status, HER2/neu status, grading and additional investigations like Ki67 and uPA/PAI1. Additionally, the treatment proposal of the respective medical expert and his or her rationale for this decision are entered.

The decision rules were validated by structured expert-interviews, carried out by two of the authors. They were arranged in a hierarchical order based on the clinical importance of the respective input parameters as they are handled in every day clinical decision-making. The extraction and hierarchical arrangement of the rule-base was predominantly performed by a consultant obstetrician and gynecologist, former head of a department for Obstetrics and Gynecology of a Regional Hospital and former Vice President of a federal state Breast Centre certified by the German Cancer Society. Based on the clinical data entered, the system generates one of five possible treatment proposals:

- Adjuvant chemotherapy,
- Adjuvant chemo- and anti-HER2 therapy,
- Adjuvant chemo-, anti-HER2- and endocrine therapy,
- Adjuvant chemo- and endocrine therapy or
- Exclusive endocrine therapy.

In cases where no ECOG performance status was documented, the system was programmed to generate a note that the patients' comorbidities and their general condition should be considered. For practical reasons the system classified then these patients' ECOG performance status as ECOG 2. After establishing and validating the rule-base of our system as described above, we tested the system's reliability, applying 100 anonymized and complete datasets from a state tumor center.

#### User interface

The web-based prototype has been the result of previous work [24] and has been created with PHP and HTML. The view has been clustered into three parts: Patient-related parameters, Tumor-related parameter, and Treatment. At first, an ID, the age, the menopausal state and ECOG state are required. The second part considers T-classification, N-classification, Hormone receptor state, HER2/neu state, Grading, additional investigations (like UPA/PAI1 or Ki67) and optionally the Nottingham Prognosis Index. The third part has the treatment proposal (in a drop-down menu) and the explanation "why this treatment has been chosen". We have added some data to the prototype—an ID, the age of 68, a post-menopausal state, an ECOG of Grade 1, a T2 tumor, a negative lymph node state (N0), a positive hormone receptor and HER2/neu state and a Grading of G3. The recommended treatment for this case is a chemo- anti HER2 and endocrine treatment. Figure 2 shows a snapshot of the prototype with the named parameters.

### Application of the prototype

The testing of the rule base of the prototype focuses on physicians' decisions from the past. The data sets have been entered into the system manually. The prototype has been implemented to support medical experts in their treatment decisions. The selected data had the following patients' characteristics: The mean age of the 100 patients, whose data derived from the tumor database, was 65 years: 12 cases were pre-menopausal and 88 cases were post-menopausal. 73 cases were N0, 16 were classified as N1, four as N2 and seven as N3. In terms of our prototype this result means, that 73 cases had a negative and 27 cases a positive lymph node-status. Concerning grading 16 were classified as G1, 72 as G2 and 12 were G3. HR-state was positive in 92 cases and negative in 8 cases, HER2/neu state was positive in 17 cases and negative in 83 cases.

For practical reasons we arranged our data in three categories based on the tumor grading. Tables 2, 3 and 4 summarize the expression of the different tumor related factors, based on the defined grading-categories. In the last column of the tables the actual physicians' decisions (treatment expert) are compared to the systems suggestions (treatment system). Thirteen of the G1 tumors had a positive hormone receptor (HR-) status, a negative HER2/neu expression and a negative lymph node (LN-) status respectively. None of the patients of our sample had a negative HR-status. Two cases had a positive HR and a positive HER2/neu-status and a negative LN-status. One case had a positive HR- and LN-status while the HER2/neu-status was negative. In all low risk cases (HR positive, G1) the system's treatment proposals matched with the experts' decisions (cp. Table 2).

72 cases had a grading of G2. 42 of these had a positive HR-status, a negative HER2/neu-status and a negative LN-status, 19 cases were HR positive, HER2/neu negative and LN positive. Three cases had a negative HR HER2/neu and LN-status. Three further cases were HR and HER2/neu positive with a negative LN-status. Three cases had a positive HR, HER2/neu-state and LN-status. One case was HR and HER2/neu negative with a positive

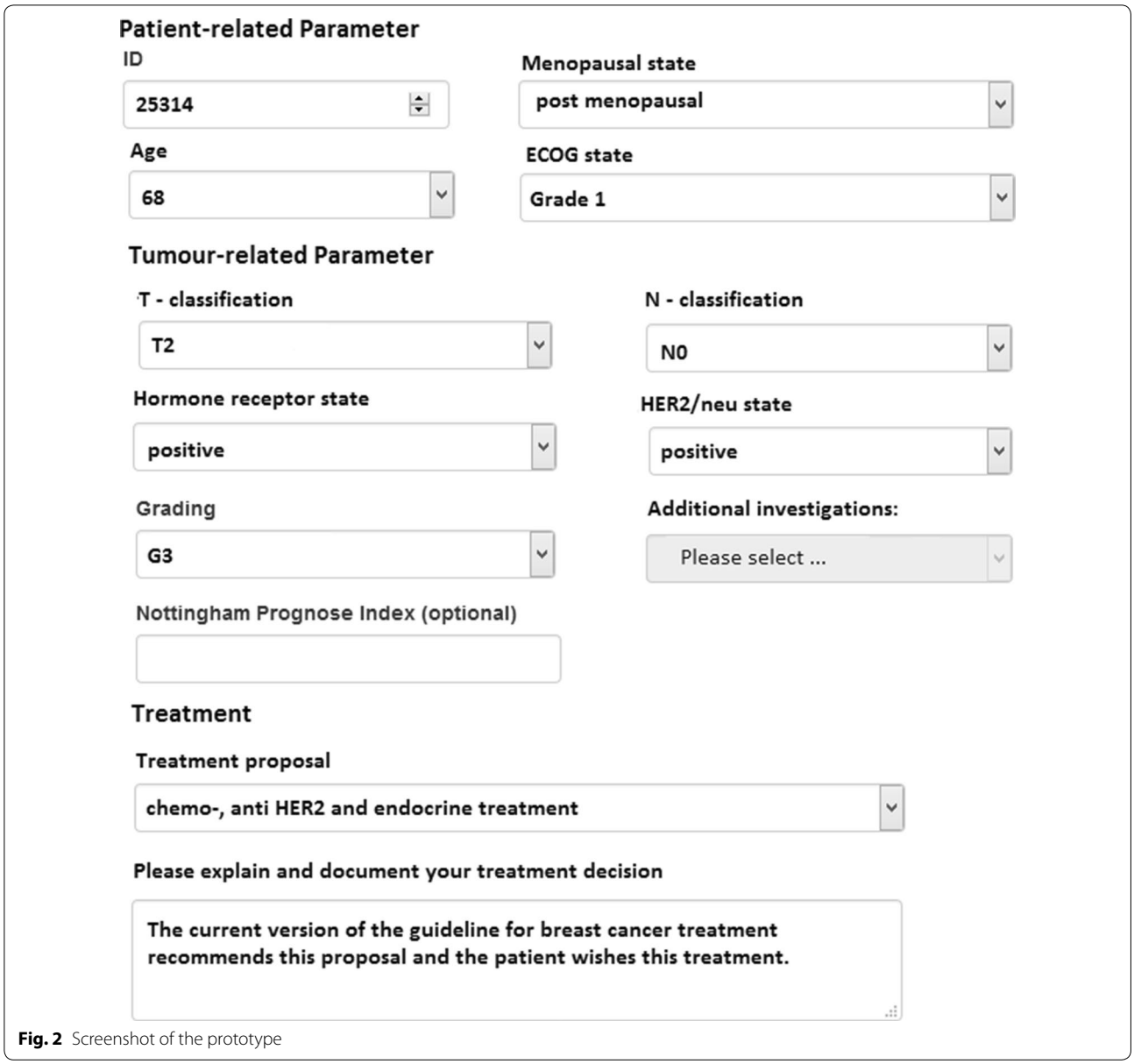


**Fig. 2** Screenshot of the prototype

**Table 2 Grading G1 cases**

| Row | Count | HR state | HER2/neu state | Lymph node state | Treatment expert/system | Congruency between both proposals? |
|---|---|---|---|---|---|---|
| 1 | 13 | + | − | − | E/E | Yes |
| 2 | 2 | + | + | − | C + T + E/C + T + E | Yes |
| 3 | 1 | + | − | + | E/E | Yes |

LN-status. The last case in the table has a negative HR and LN-status and a positive HER2/neu-status. Table 3 lists the G2 cases comparing the treatment proposal of the experts and the system, as well as the congruency between both.

Concerning the G2-category, there was a larger number of deviations between the system's proposals and the physicians' decisions: Surprisingly, only in 36 of 72 cases the system's proposal matched with the actual clinical decision (every row with a Yes). The first and the second-row

**Table 3 Grading G2 cases**

| Row | Count | HR state | HER2/neu state | Lymph node state | Treatment expert/system | Congruency between both proposals? |
|---|---|---|---|---|---|---|
| 1 | 27 | + | − | − | E/C + E | No |
| 2 | 15 | + | − | − | C + E/C + E | Yes |
| 3 | 12 | + | − | + | C + E/C + E | Yes |
| 4 | 7 | + | − | + | E/C + E | No |
| 5 | 3 | − | − | − | C/C | Yes |
| 6 | 3 | + | + | − | C + T + E/C + T + E | Yes |
| 7 | 2 | + | + | + | E/C + T + E | No |
| 8 | 1 | − | − | + | C/C | Yes |
| 9 | 1 | + | + | + | C + T + E/C + T + E | Yes |
| 10 | 1 | − | + | − | C + T/C + T | Yes |

**Table 4 Grading G3 cases**

| Row | Count | HR state | HER2/neu state | Lymph node state | Treatment expert/system | Congruency between both proposals? |
|---|---|---|---|---|---|---|
| 1 | 2 | + | + | + | C + T + E/C + T + E | Yes |
| 2 | 2 | + | − | − | C + E/C + E | Yes |
| 3 | 3 | − | + | − | C + T/C + T | Yes |
| 4 | 2 | + | + | − | C + T + E/C + T + E | Yes |
| 5 | 1 | + | + | + | E/C + T + E | No |
| 6 | 1 | + | − | − | E/C + E | No |
| 7 | 1 | + | − | − | C/C + E | No |

cases had a positive HR- and negative HER2/neu and LN-status respectively, we found divergent results (42 cases). Since the system graded G2 as "high risk" it favored a combination of chemo and endocrine treatment while the physicians obviously classified the combination of G2, HR positive and HER2/neu and LN negative as "low risk" indicating an exclusive endocrine treatment (27 cases). However, in 15 of these identical cases both, the system and the physicians, came to the same decisions. The third and fourth row cases had a positive HR, a positive LN status and a negative HER2/neu status (19 cases). The system's proposals do not match in 7 cases with the actual decisions, while in 12 cases the decisions are identical. The seventh and the ninth-row cases had a positive HR, HER2/neu and LN state (3 cases). The system's proposal was chemo-, antiHER2 and endocrine therapy, in one case this decision matches with the physicians' recommendation, but in two cases the physicians' recommendations was an exclusive endocrine therapy.

We had also 12 cases with a grading of G3. 3 of 12 cases had a positive HR, HER2/neu and LN- status. 4 of 12 cases had a positive HR state and a negative HER2/neu and LN- status. 3 of 12 cases had a negative HR and LN-status and a positive HER2/neu status and 2 of 12 cases had a positive HR and HER2/neu state and a negative LN- status. Table 4 shows the G3 cases with the treatment proposals of the experts' compared with the system's proposals, as well as the congruency between both.

In 9 of 12 cases in the G3-category, the physicians' recommendations and the system's proposal matched (every row with a Yes), leaving 3 non-matching cases (every row with a No). Three cases had a positive HR, HER2/neu and lymph node state (row 1 and 5) where the system proposes a chemo, anti-HER2 and endocrine treatment, in two cases this proposal fits with the physicians' recommendations, in one case the physician recommended an endocrine treatment only. In four cases the hormone state is positive, HER2/neu and lymph node is negative and the systems proposal is a chemo and an endocrine treatment (row 2,6 and 7), in two cases the physicians' proposals matched with the systems proposal, in two cases not. In one case the physician recommended an endocrine treatment and in the other case an exclusive chemotherapy was recommended.

About the G1 category (Table 1) it is important to note that all deviating index cases had a positive HR-state. This assumes that the physicians' decisions are based predominately on the factors G1 and HR positive. Much more difficult is the interpretation of the diverging results in the category G2-tumors (cp. Table 3). Possible

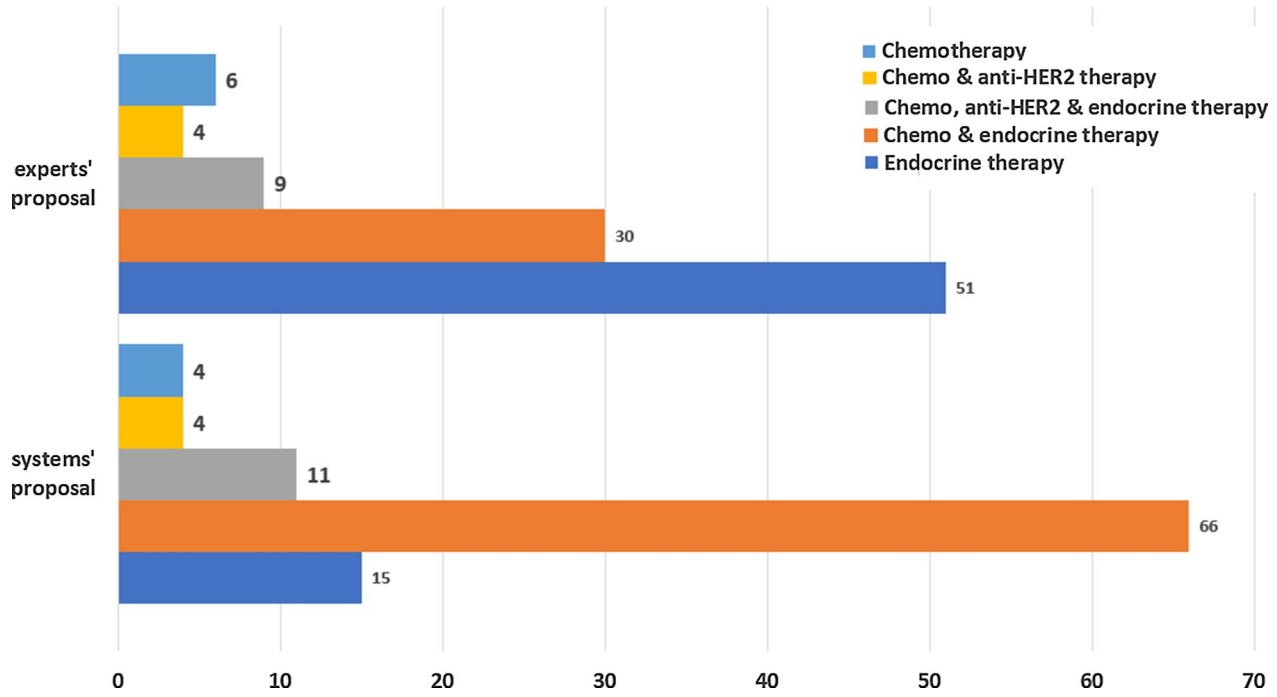


**Fig. 3** Experts' and system's decisions

reasons for the differences in the physicians' recommendation and the system's proposals could be the age of the patients (which was on average 73 years in this group), comorbidities and/or the general health conditions of the patients not further specified in the patient records [25]. Moreover, it should be kept in mind, that according to the recommendations of the St. Gallen Consensus Conference in cases of intermediate risk (which group consists predominately of G2 and HR positive tumors) both modalities, the exclusive endocrine treatment, or the sequence of chemotherapy followed by endocrine treatment are judged as equally effective.

Concerning the G3 category we found deviating recommendations in three cases. However, two of these patients were older than 80 years with several comorbidities noted. In the remaining case of a 52 years old patient no obvious reason for the discrepant decision could be found.

Figure 3 compares the physicians' decisions with the system's proposals. While the experts indicated a chemotherapy (C) in five cases (5%), a chemo- and anti-HER2 therapy (C + T) in four cases (4%), a chemo-, anti-HER2 and endocrine therapy (C + T + E) in nine cases (9%), a chemo and endocrine therapy (C + E) in 30 cases (30%) and an exclusive endocrine therapy (E) in 52 cases (52%), our system proposed in four cases a chemotherapy (4%), in a further four cases a chemo- and anti-HER2 therapy (4%), in twelve cases a chemo-, anti-HER2 and endocrine therapy (12%), in 66 cases a chemo- and endocrine therapy (66%) and in 14 cases an exclusive endocrine therapy (14%), cp. Figure 3.

Table 5 summarizes and compares the experts' and the system's decisions and obviates the disagreement.

While the proposals of the system's and the physicians' decisions are almost identical in case of an exclusive chemotherapy (physician 6% and system 4%), and match completely for the chemo- and anti-HER2 therapy, the situation is quite different for the other decision classes. The physicians recommend a combination of chemo-, anti-HER2 and endocrine therapy in 9%, the system proposed the same treatment in 11%. While the physicians recommend C + E in 30% of all cases, the systems proposed this treatment for 66% of the patients. Even worse is the deviation between the physicians'

**Table 5 Comparison of experts' and system's decision**

| Treatment | Experts | System | Discrepancy |
|---|---|---|---|
| Chemotherapy | 6 cases | 4 cases | 2 cases |
| Chemo- and anti-HER2 therapy | 4 cases | 4 cases | None |
| Chemo-, anti-HER2 and endocrine therapy | 9 cases | 11 cases | 2 cases |
| Chemo + endocrine therapy | 30 cases | 66 cases | 36 cases |
| Endocrine therapy | 51 cases | 15 cases | 36 cases |

recommendations and the system's proposal in cases of an exclusive endocrine treatment: 51% versus 15% respectively. This however could be attributed to an erroneous decision rule of the system: We implemented the rule that if no ECOG status (as indicator of an impaired overall health status) was documented, the system proposes the more aggressive type of treatment but advocates the user to have a look at the general condition and comorbidities of the patient. Especially in the cases of chemo- and endocrine therapy this could have had a major impact on the resulting differences. Therefore, the rule-base will have to be adjusted, resulting in "softer" decisions, especially if some information is missing in the datasets—like the ECOG state.

We cannot yet trace how physicians make their decisions in certain cases. The system generated reliable treatment proposals for G1 and certain G3-cases, though not for G2. The rationale for the deviating physician treatments (proposals) needs further investigation of those cases.

## Discussion, lessons learnt and future work

We have elicited a medical process and extracted the decision rules from guidelines, and embedded them into the prototype. We then used the prototype with some data to compare the expert decisions with our automatically generated decision recommendations. In conclusion we realized that—especially in the cases of intermediate grade tumors (G2)—our rule-base had been modeled too strict.

The representation of this rule was based on the patients' ECOG status, which however was only documented in a minority of all cases. Moreover, we realized that the construction of the rule-base was much more time-consuming as expected in the first instance. We therefore concentrated our efforts on implementing the rules in the system's source code. This however makes it difficult to overlook all possible changes in the code, once changing any of the input parameters is found to be necessary. The next generation prototype will therefore apply a rule-engine. We will re-prototype our first version and change the settings and rules for that.

Furthermore, the rule-base must be revised and then re-validated by medical domain experts. The definition of the mandatory field 'ECOG status' will have to be changed, because this item—although found to be very important by us and others [25]—was documented only in a very few cases. However, it could be very useful to add this factor in future tumor documentation files, since it reflects the patient's overall health status, and may thus be a crucial point for individualized treatment decisions [8]. Taking a critical view on our preliminary results, we conclude that our implemented rule-base results in rather aggressive treatment proposals of our system, leaving no space for any variations in the decision process. Therefore, a reconsideration of our implementations, e.g., by using case-based reasoning, could be useful. The validation of the decision rules supported by a rule-engine (e.g., drools) is the next step necessary. A user acceptance test will also be useful and necessary. After the system had been constructed, the result was presented to an expert. However, it is evaluated to a certain extent in Section "On the design of a prototype for breast cancer treatment". Although being very subjective, this evaluation delivers a first impression if it would fit their process context. In further research we will carry out a greater empirical analysis of acceptance for the proposed approach. Medical decision support in general seems a very worthwhile approach to assist healthcare workers at least to reflect what they are doing no matter the maturity of underlying concepts. The developments of this paper might be promising, but our work is just a first step to improve and support processes and their decision rules as well as its documentation. The chosen approach shows us, that the realization of a clinical decision support system is not so easy. The individual factor human being is a major issue in our prototype—and it must be considered—we tried to use ECOG state for this, but the problem was that it wasn´t documented. Furthermore, the rule-base must be revised and then re-validated by medical domain experts. The definition of the mandatory field 'ECOG status' will have to be changed, because this item—although found to be very important by us and others [25]—was documented only in a very few cases. However, it could be very useful to add this factor in future tumor documentation files, since it reflects the patient's overall health status, and may thus be a crucial point for individualized treatment decisions [8]. In our future work we will try to find the optimal approach for the breast cancer treatment.

## Conclusion

Decision support in medicine is a very complex topic. The human factor makes it hard to create a decision treatment matrix for all individual patients. The transparent representation od decision patterns is just the first step for the realization of a decision support system and the decision rules must be revised and revalidated. The documentation of all parameters is another major thing, that needs to be changed in our future work. We think that workflows and decision support belong together: that is why model-based decision support and documentation are of utmost importance and play a key role.

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