Selecting Image-Guided Surgical Technologies in Oncology: A Surgeon’s Perspective

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Abstract
Background: To improve surgical performance, image-guided (IG) technologies are increasingly introduced. Yet, it is unknown which oncological procedures yield most value from these technologies. This study aimed to select the most promising IG technology per oncologic indication.

Methods: An Analytic Hierarchical Process was used to evaluate three IG technologies: navigation, optical imaging, and augmented reality, in five oncologic indications compared with usual care. Sixteen decision criteria were selected. The relative importance of the criteria and the expected performance of the technologies were evaluated among surgeons. The combination of these scores gives the expected value per technology.

Results: On criteria level, sparing critical tissue (9%-18%) and reducing the risk of local recurrence (11%-27%) were most important. Navigation was preferred in three indications—removal of lymph nodes (42%), liver (47%), and rectal tumors (33%). In removing rectal tumors, optical imaging was equally preferred (34%). In removing breast and tongue tumors, no technology was clearly preferred.

Conclusions: In selecting IG technologies, especially optical and navigation technologies are expected to add value in addition to usual care. Further development of those technologies for the preferred indications seems valuable. Multi-attribute analysis showed to be useful in prioritization of conducting clinical studies and steer research and development initiatives.

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Synopsis: IGs is very promising in the oncologic field. Our study systematically evaluated what to expect from certain technologies for the removal of lymph nodes and liver, rectal, breast and tongue tumors among surgeons to guide further research and development.

Data availability statement: Most of data used for the present analysis are included in the article and supplementary material. The data that further support the findings of this study are available from the corresponding author upon reasonable request.

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**Introduction**

Effective resection of advanced malignant tumors can be challenging, which thereby could result in an increased risk for (local) recurrence depending on tumor origin. As (local) recurrences have an impact on the quality of life, health care costs, and chance on survival, improving surgical performance is of high clinical and economic importance.

Recently, image-guided surgery (IGS), which integrates imaging modalities such as computed tomography and magnetic resonance imaging in the surgical environment, was introduced to improve surgical performance. The hypothesized benefit of IGS is an improvement in surgical performance and reduce the risk of secondary procedures by enabling intraoperative evaluation of surgical success (e.g., surgical margin status), and ultimately improvement in clinical outcomes. The use of IGS in oncology could, for instance, enable intraoperative evaluation of surgical margin status. Considering that the risk of recurrence is associated with positive surgical margins, IGS could play an important role in the future. Although it has a high potential for oncology, IGS has not been introduced widely. This may be explained by the limited ability of the available imaging techniques in the operating room (C-arm cone beam computed tomography [CBCT], ultrasound, and magnetic resonance imaging) to accurately visualize the tumor, its boundaries, and its critical surroundings. Therefore, medical device companies and several research groups seek for new technical solutions that could provide the image guidance needed in oncologic surgery (e.g., probes and navigation technologies). The development of these technologies and the subsequent evaluation in terms of safety and efficacy per tumor type is time consuming. This is especially the case as the clinical evaluation is known to be challenged by factors as learning curve, user interactions, and frequent product modifications. To stimulate targeted development and guide the clinical evaluation of these technologies, early evaluation of the potential of these technologies for the interventions of interest would be valuable.

Health technology assessments (HTAs) can be used to systematically evaluate social, clinical, ethical, organizational, and economical aspects of new technologies and are mainly used to inform decision-making processes (e.g., reimbursement). For HTA on medical devices, an iterative approach has been suggested, as devices are known to be frequently adapted and may become of use for other indications and prices are likely to change over time. One of the methods used, especially in an early stage, is a Multiple Criteria Decision Analysis (MCDA), which is a method used in complex decision-making. This study aimed to select the most valuable image-guided (IG) technology per indication of three promising IG technologies targeted at the oncologic setting by means of MCDA to inform ongoing and new research and development initiatives.

**Methods**

Several types of MCDA exist to evaluate new interventions in an early stage. In this analysis, the Analytic Hierarchical Process (AHP), which is often applied to inform health care decision problems, was selected as an appropriate method. The steps followed are presented in Figure 1.

In this AHP, we focus on five indications: surgical removal of breast, rectal, tongue and liver tumors and lymph nodes for which the following three newly developed IG technologies that are expected to improve surgical outcomes are currently being tested in the Netherlands Cancer Institute—Antoni van Leeuwenhoek hospital (NKI): navigation technology, optical imaging (spectroscopy), and augmented reality. In addition, the standard of care per indication was included to evaluate the added value of the technologies compared with standard of care. In an AHP, first decision criteria are chosen (Identification of decision criteria section). Second, the importance of the criteria is evaluated (Relative importance of criteria section). Third, the expected performance of the four alternatives (technologies) is evaluated per indication on the chosen decision criteria (Description of the IG technologies of interest, relative performance, and relative value section).

**Identification of decision criteria**

In Step 1, the decision criteria were chosen. We identified decision criteria relevant to all indications and used the HTA core model for medical and surgical interventions by EUnetHTA. We identified four domains: effectiveness, efficiency, technical, and organizational. In addition, some subcriteria, such as workflow, training, and capacity, were identified. Furthermore, recent clinical guidelines per indication were checked to identify clinically relevant criteria for all indications, for example, the sparing of critical tissue surrounding the tumor and the reduction of the risk of local recurrence. The draft set of criteria was discussed in a face-to-face meeting among a team of surgeons (experienced in one or more of the disease areas) and technical developers/researchers involved in the development of one of the IG technologies on completeness and redundancy. Their feedback was discussed by M.L. and V.R. The set was adapted accordingly when a consensus was reached and finally checked on overlapping criteria. The final set contains 16 criteria that were expected to influence the success of IG technologies in the chosen indications (Fig. 2). After discussing our research design with the institutional review board, they waived formal assessment because no patients were included in our research setup.

**Relative importance of criteria**

Because of tumor-specific challenges, the relative importance of the 16 criteria is expected to vary per indication. The importance of the criteria was evaluated per indication among surgeons in the NKI specialized in one or more of the five indications in the beginning of 2018 (Table 1). In a face-to-face interview, they were asked to pair-wise compare the criteria...
on a reciprocal rating scale. The questionnaire used in this interview contained 37 questions. All criteria were explained to each surgeon before the pair-wise comparison to ensure that the interpretation was similar. The definitions are listed in Supplement 2. The individual results from the evaluation were sent back to the surgeon to validate whether these numbers reflected their ideas. If necessary, the initial ratings were adapted accordingly.

After all individual rounds, an extra round of feedback was held among the participating surgeons to reach consensus using an overview of their scores and the scores of their colleagues. This additional round was held to mimic a group meeting, which is mainly used in MCDAs to stimulating group discussions and allowing to reach consensus. We highlighted substantial differences between the individual estimates and the group estimates. The surgeons were able to adapt the final values and asked to describe reasons for a change or the initial value in case of no change.

Description of the IG technologies of interest, relative performance, and relative value

The technologies of interest are currently only used in a research setting, and therefore, no comparative data are available yet. For that reason, 20 surgeons having experience with at least one of the technologies were asked to express the expected performance of the three IG technologies and usual care on each of the criteria. The experience with the technologies was thought to be required to evaluate the experienced ease of use and expected advantages. To enable

Fig. 1 — Schematic visualization of the AHP process.
comparison, the working principle of each technology was described in detail together with the technical developers. The definitions used are presented in Table 1. For evaluation of the technologies on the criterion “intervention costs,” a first noncommercial estimation of the costs per patient was calculated by estimating equipment costs and additional material and labor costs per technology. In this second round of interviews, also in the beginning of 2018, each surgeon was asked to pair-wise compare the technologies and usual care on the 16 decision criteria. After the interview, the retrieved values were fed back to the surgeon to validate the ranking of the alternatives and the differences between the alternatives. If these values were not reflecting their opinion, the results were adapted accordingly.

Based on the individual responses, average importance and performance scores per indication were retrieved using the geometric mean. Combining the importance of the criteria and the expected performance on each criterion resulted in a sum score of the technologies and usual care. The sum score per technology is a relative percentage showing the expected relative value compared with the other technologies and usual care. This sum score was calculated for both the full criteria set and the effectiveness domain only.

Analysis

To identify differences in the relative importance of the criteria and relative expected value of the technologies between the five interventions, the standard error (SE) was used. When there was no overlap between two SEs of one criterion in a certain intervention and the same criterion in the other interventions, that criterion was judged as more or less important. The same approach was used to decide whether one technology was preferred in a specific intervention.

In addition, sensitivity analyses were conducted. In the first analysis, the importance of each criterion was varied with ±2 SEs and measured the influence on the expected relative value by evaluating the robustness of the preferred technology per indication. In the second analysis, the importance of the effectiveness domain was varied over a range of 20%-80%, and the importance of the other domains was adapted according to the initial importance scores.

Results

Relative importance of decision criteria

In total, 18 surgeons evaluated the importance of the decision criteria, and 12 of 18 participated in the final feedback round, reaching an overall consensus of 83%. In Supplement 1 the characteristics of the surgeons are listed.

Surgeons value the effectiveness domain the highest when evaluating the value of new IG technologies (59%-66%), followed by the technical (13%-21%), efficiency domain (12%-17%), and the organizational domain (4%-12%). Figure 3 and Supplement 3 show the relative importance of each criterion per indication. Among the 16 criteria, “sparing critical tissue” (9%-18%) and “decreasing risk of local recurrence” (11%-27%) are expected to have a high impact on the value of the IG technology in all indications. Specifically for lymph node removal, “decreasing risk of distant metastasis” is expected to have a high influence (13.7%), and for breast cancer surgeries, “improving patient satisfaction” seems to play a major role (16.2%). In addition, among all indications, the influence on the workflow, risk on technical failures, a high ease of use, and improved decisiveness were evaluated as important criteria for the success of a new technology. The observed differences among indications are highlighted in Figure 3.

Fig. 2 – Decision criteria framework. The decision criteria used to evaluate the value of a new IG technology in five indications. The framework was based on the HTA core model for medical and surgical interventions, literature, and group discussions with experts. The arrows describe the direction of the desirable influence which would be classified as added value for the technology. For example, a reduction in local recurrence rate (1.1).

![Decision criteria framework](image-url)
Table 1 – Definitions of the three technologies of interest.

<table>
<thead>
<tr>
<th>Technology</th>
<th>Definition</th>
<th>Pictures</th>
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<tbody>
<tr>
<td>Usual care</td>
<td>This is defined in the first interviews by the clinicians per intervention. For example, in breast tumor resection, the use of the radio-active seed localization is part of current clinical practice.</td>
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<tr>
<td>Navigation</td>
<td>Technology providing a three-dimensional anatomic model that can be linked to the current situation in the operating room by using the CBCT scanner in the operating room. The pointer can be located by electromagnetic technology, which is linked to the three-dimensional anatomic model. This enables navigating to the locations of interest.</td>
<td></td>
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<tr>
<td></td>
<td>- The model shows an accuracy of at least 5 mm</td>
<td></td>
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<tr>
<td></td>
<td>- Surgery has to take place in the hybrid operating room</td>
<td></td>
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<tr>
<td></td>
<td>- Before or during surgery an extra CT scan is made to link the model to the current situation. This result in a 15-min delay of the surgery.</td>
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<tr>
<td></td>
<td>- Additional costs per patient are estimated between €1750 and €3070 (depending on the utilization of the technology and CBCT)</td>
<td></td>
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<tr>
<td>Optical imaging (spectroscopy)</td>
<td>This technology that can assess characteristics of tissue (molecular) during a surgery by using the principles of scattering and absorption of light. It can be used in two different clinical situations: (1) as a surgical knife that includes optical fibers that can identify during resection whether the resection takes place in benign or malign tissue and (2) a hyperspectral camera that is used after resecting a certain specimen to check whether the resection margins are clean (ex vivo). This camera can also be used in a laparoscopic setting to also discriminate benign from malign tissue during the intervention (in vivo).</td>
<td></td>
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<tr>
<td></td>
<td>- The accuracy to identify the type of tissue correctly is at least 90%</td>
<td></td>
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<tr>
<td></td>
<td>- For the in vivo and ex vivo measurements, the OR lights should be adjusted to obtain accurate results. This results in at least a delay of 10-15 min</td>
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<td></td>
<td>- Additional costs per patient are estimated between €700–€1300</td>
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Relative performance and relative expected value of the IG technologies

Seventeen surgeons evaluated the IG technologies and usual care on the decision criteria, of which the results are presented in Supplement 4. These spider plots show that surgeons expected that especially navigation could improve their performance in liver, rectal, and tongue tumor resection and lymph node dissection on “sparing critical tissue,” “improving patient recovery,” “decreasing the risk of complications,” and “being more decisive.” In addition, for tongue and rectal tumor resection, optical imaging is expected to “reduce the risk of local recurrence.” In removing breast tumors, usual care is on most of the criteria preferred over the three technologies, but the surgeons expected that navigation could improve “patient satisfaction” and “decisiveness.”

Table 2 and Figure 4 show the expected relative value of the IG technologies and usual care per indication when taking all the decision criteria into account. In removal of liver tumors and lymph node dissection, navigation is preferred (47%, 42%) over usual care (16%, 17%), optical imaging (21%, 18%), and augmented reality (17%, 22%). In rectal cancer, both optical imaging (34%) and navigation (33%) are preferred over usual care (16%) and augmented reality (17%). In removing tongue tumors, all IG technologies are preferred (26%, 27%, and 28%) over usual care (19%), although the difference between usual care and the technologies is small. Finally, in removing breast tumors, navigation and usual care were preferred equally, with 27% and 26% respectively. The expected added value for the use of IG technologies seems thus rather low.

For breast cancer, an additional analysis was conducted because the low expected added value may be explained by the composition of the criteria set. During the interview, breast cancer surgeons suggested adding a criterion incorporating the risk of reoperations. Assuming the relative importance of this new criterion equal to “the risk of local recurrence” (11%) and replacing the performance of “risk of local recurrence” by the performance on “risk of reoperations” resulted in a higher expected relative value for navigation (29%) compared with usual care (25%), optical imaging (23%), and augmented reality (23%) than in the initial analysis.

Figure 5 shows the expected relative added value of the alternatives when only the effectiveness domain (relative importance and relative performance) is considered. For effectiveness only, navigation was preferred over usual care in removing rectal, tongue, and liver tumors, and lymph nodes and optical imaging were preferred over usual care in the removal of rectal tumors.

Sensitivity analyses

The uncertainty surrounding the relative importance scores of the criteria showed no major changes in the order of the preferred alternatives per intervention. The preferred option changed only in breast and rectal cancer on some criteria mainly because of a similar initial relative expected value. Ranging the importance of the effectiveness domain shows that it could influence the preferred technology (Supplement 5). For example, when the effectiveness domain explains at least 60% of the value of a technology in tongue cancer,
Fig. 3 – Relative importance of the decision criteria per indication. The importance of the decision criteria to evaluate the added value of image-guided technologies shown per indication as evaluated by the surgeons. (A) The results for the effectiveness domain. (B) The results for the efficiency, technical, and organizational domain. The shown percentages were retrieved by multiplying the importance of the domain and the importance of the individual criteria in that domain.

*Decision criteria that have more or less influence on the expected value of the technology compared to the other indications. (Color version of figure is available online.)

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Table 2 – Expected relative added value of each technology per intervention.

<table>
<thead>
<tr>
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<th>Average score (±2 SEs)</th>
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<tbody>
<tr>
<td></td>
<td>Lymph node dissection</td>
</tr>
<tr>
<td>Navigation</td>
<td>0.42 (0.25-0.6) [1]</td>
</tr>
<tr>
<td>Optical imaging</td>
<td>0.18 (0.1-0.26) [3]</td>
</tr>
<tr>
<td>Augmented reality</td>
<td>0.22 (0.11-0.34) [2]</td>
</tr>
<tr>
<td>Usual care</td>
<td>0.17 (0.09-0.26) [4]</td>
</tr>
</tbody>
</table>

*This table shows the relative added value scores of each of the alternatives including the range (±2 SEs).

The values within square brackets show the ranking of the alternatives, with 1 representing the favored option for that indication.

*The relative value score and its range showed no overlap with the relative value score and range for usual care (±2 SEs).
navigation is preferred. Below 60%, augmented reality is preferred.

**Discussion**

This study provides valuable insight into the potential to select IG surgical technologies used in surgical oncology from a surgeon’s perspective.

Based on the relative importance results, the added value of an IG technology is mostly explained by the effectiveness domain (at least 59% importance). Therefore, we may conclude that out of a surgeon’s perspective, innovative surgical technologies should improve clinical outcomes to become successful. In addition, for the success of technologies, we identified that they should show no (or a small) influence on the workflow, a small risk of technical failures, high ease of use, and an improved decisiveness during surgery (Fig. 3 and Supplement 3). The differences in relative importance per indication can be used to steer the development of new and existing IG technologies. Finally, the setup for the present analysis could be used to evaluate the benefit of surgical technologies again in a later stage when more data are available (iterative approach).

Based on the expected relative value per technology, research and clinical research projects can be prioritized.

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**Fig. 4** — Expected relative value of IG technologies per intervention. Showing the relative expected value of each alternative per intervention. The relative expected value is the result of combining the relative importance of the decision criteria and the expected performance of each alternative on those criteria. The relative value score and its range showed no overlap with the relative value score and range for usual care (±2 SEs). (Color version of figure is available online.)

**Fig. 5** — Expected relative value of IG technologies per intervention: effectiveness domain. Showing the expected relative value per technology per intervention when the effectiveness domain would define the total value of the technology. The relative value score and its range showed no overlap with the relative value score and range for usual care (±2 SEs). (Color version of figure is available online.)
Navigation is expected to add the most value in lymph node dissections and removal of rectal and liver tumors. Hence, our results suggest that the development of navigation technologies should focus on those tumor types. After this, pilot studies and comparative observational studies are needed to evaluate its safety and efficacy. The results on the expected performance (Supplement 4) can inform the choice of relevant outcome parameters. The same applies to optical imaging in resecting tongue and rectal tumors and for augmented reality in tongue tumor resection. Regarding these recommendations, one should keep in mind that not all oncologic specialties were included in the evaluation, and therefore, we cannot guide nor cover the full development process. Besides, related to the phase of development, as the surgeons were—except for the description of the technology—quite unfamiliar with the full potential of the technologies, so the expected relative performance should be interpreted with caution. For removing breast tumors, our results cannot really guide further development, as no preferred technology was found. This may be explained by the already highly adequate surgical performance, by which criteria in favor of usual care (e.g., costs, capacity, and workflow) were considered relatively more important than in the other interventions. Besides, the value of IG technologies could be underestimated as shown by the additional analysis incorporating “risk of reoperations.”

It should be noted that the strong relative preference for navigation could be biased, as the included surgeons had relatively more experience with the navigation technology than with optical imaging and augmented reality. This is because optical imaging is in the preclinical study phase, and for augmented reality, just recently the first feasibility studies are conducted. Therefore, the included surgeons may not have been able to oversee the range of benefits that they may experience when using optical imaging and augmented reality. All participating surgeons had, however, a similar level of experience with the three technologies; therefore, we were unable to check whether the preference for a specific technology is explained by the level of experience. Recently, a study showed that surgeons were very enthusiastic about the use of augmented reality in renal cell carcinoma when evaluating surgical performance (e.g., assessment of critical structures). In addition, the included head and neck surgeons—who are using three-dimensional models (digital or phantoms) in current clinical practice—were positive on the use of augmented reality in tongue cancer. It seems plausible that the inexperience of the surgeons could thus have underestimated the added value of both optical imaging and augmented reality in this study. In our opinion, this effect was hard to prevent, as these technologies are very innovative, and therefore, incorporating surgeons having experience with all technologies was not possible.

One of the strengths is that the expected added value of these IG technologies was retrieved from the end-users’ perspective and in perspective of usual care. We especially feel this as a strength with regards to the relative importance results. In addition, the broad decision criteria framework used was a strength, as the set enables evaluation of clinical-, process-, and technical-related criteria, which are important determinants in the successful implementation of technologies. This framework creates a rather negative scenario for the IG technologies by which the technologies have to show substantial benefit to be preferred over usual care. Finally, by using one criteria framework, for all indications, our analysis was able to pinpoint at differences between indications that feed research and development of those technologies.

This study has some limitations. The institutional focus limits the generalizability of our results, especially of the relative importance of the decision criteria. Nonetheless, incorporating the uncertainty surrounding the importance scores in the sensitivity analyses did not alter our conclusions. The small number of surgeons included per intervention (≥3) should be noted, as the sample might not be representative for the Netherlands or other countries. We were, however, limited to include surgeons having relevant knowledge on the technologies to provide a reasonable estimate of the added value of those IG technologies. To increase the generalizability of the importance scores, in a future study, the importance of the decision criteria should be tested among a larger population of surgeons, preferably among an international sample. Furthermore, as previously touched upon, especially the results from the relative performance could be subject of bias, as surgeons were still unfamiliar with the use of optical imaging and augmented reality. However, we feel that this was the best information we could retrieve at this stage in the development process and may be used with caution to guide further development. The final issue is related to the early nature of this evaluation. As specific applications of these technologies are yet unknown, a very general evaluation of the technologies by only describing the tumor type and not specifying tumor stage or a specific surgery (e.g., lower anterior resection) was conducted. In future analyses, the technologies should be evaluated for specific cases.

As early stage HTA research can be seen as an iterative process, the future research steps follow the development process of the technologies. The next step will, therefore, be to evaluate the added value of each technology per indication based on the first clinical results. In a later phase, the presented analyses can be updated with the most recent data. For example, for the indication lymph node dissection, a randomized controlled trial was started comparing surgical success of lymph node removal with navigation and without (usual care), with the aim to also evaluate the cost-effectiveness of navigation use. Furthermore, in colorectal cancer patients, an observational study has been performed, showing improved negative resection margin rates with navigated surgery compared with standard surgery in a historical control group. Based on these results, an early cost-effectiveness analysis was performed, showing that navigation has the potential to become cost-effective in specific clinical subgroups and when the navigation system is used optimally. In colorectal, liver, and breast cancer surgery, several feasibility studies have been performed for optical imaging applications and augmented reality. When clinical studies show improved clinical outcomes, early cost-effectiveness analyses will be performed to evaluate whether the added value weights up for the additional costs or
what could be improved in technology, in technology costs or indications for its use.

This case study showed a specific example of how MCDA could be used in the selection and (early) evaluation of innovative surgical technologies for further research. As surgical innovations are increasingly coming to the market and are likely to result in increased health care costs, assessment of the added value of innovations becomes more important. Based on our results, we may conclude that for lymph node dissection and liver tumor ressection, most is expected from using a navigation system in addition to usual care. For rectal cancer, both navigation and optical imaging seem to be preferred. For removal of tongue and breast tumors, no clear preference was identified. In our opinion, this study showed that multi-attribute evaluations can be useful to broadly assess the value before implementation and, therefore, enables prioritization of clinical research and further development.

Acknowledgment

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Authors’ contributions: The study was designed by W.v.H., V.R., and M.L. The data collection was performed by M.L. in collaboration with K.K. and T.H. All data were analyzed by M.L. and interpreted by and with all authors (J.v.T., V.R., K.K., T.H., and W.v.H.). M.L. drafted the article. All authors listed (J.v.T., V.R., K.K., T.H., W.v.H.) critically reviewed, and approved the article before submission.

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All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For all the interviewees (employees of the eight hospitals involved in our research), the authors asked their permission to record the interviews, and additionally, the authors checked the information retrieved from the interview with each interviewee. No patients or animals were involved in this research.

Disclosure

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jss.2020.08.003.

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