Arguments for and against Centralization in Oncologic Visceral Medicine

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Question 1: Given the fact that centralization based on quality parameters will take place, what is your suggested strategy to ensure adequate training for following doctors?

Faiss: In order to ensure adequate training in gastrointestinal endoscopy under the conditions of centralization based on quality parameters, we have to train our following doctors more than today before they start to examine patients. For such a 'pre-patient training' theoretical seminars (offered e.g. by the medical societies) as well as practical training courses in animal endoscopy (offered e.g. also by non-medical society-associated institutions) are mandatory.

Lordick: Institutions that are certified for the training of specialists in medical, surgical and radiation oncology and certified centers for the treatment of the relevant diseases in visceral medicine should be qualified. Exchange training programs for limited time periods are easy to organize, if there is a political will. This could be done for rare diseases like e.g. esophageal cancer or biliary tract cancers, where the case load is limited in some centers.

Mansky: Although medical education is a very important topic, priority in medicine must be given to patient safety and outcomes. If centralization improves outcomes, solutions which follow these medical needs have to be found for medical education. In any case medical education is increasingly specialized. Although one might regret this from an 'old-fashioned' point of view, this development is inevitable due to the development of medical knowledge. The specializa-

tion in medical education and centralization affect each other. On the one hand, the classical 'generalist' who is needed for smaller all-round departments, e.g. in general surgery or general internal medicine, will hardly be available any more in future. On the other hand, the specialist education requires more centralized departments. This means that not only quality issues but also the development of medical education itself will enforce more centralization. For the remaining needs of basic education more cooperative forms of medical education will be needed. Rotation is already a part of education in many big hospitals. It should increasingly become a part of medical education wherever it is not yet implemented. Also, this is in the interest of the young doctors who are looking for a good education.

Welsch: Quality parameters will consider hospital and surgeon volume regarding specific diseases or operations, but also outcome parameters (e.g. morbidity, hospital stay, or survival). Model- or computer-based simulator training has proven to be effective for the improvement of surgical outcome and will become mandatory. Furthermore, subspecialization at later stages of the surgical training cannot be excluded.

Question 2: Do you see a need for centralization in oncologic care? Which should be the parameters for centralization in your opinion?

Faiss: In general, there is a need for centralization in medicine and especially in oncologic care. In the future, gain of knowledge in

oncologic care will increase dramatically. Innovative therapeutic agents as well as new, less invasive diagnostic and therapeutic methods will change conventional oncologic care. Therefore, specialists for different diagnostic and/or therapeutic approaches are needed in order to provide patients with the best available medical therapy. In conclusion, specialization is leading to centralization. However, reliable prediction of parameters for centralization besides case load and quality and/or outcome parameters is rather difficult.

Lordick: Complex oncological diseases are the best example where centralization makes sense. It is in the interest of our patients in terms of survival outcomes and of the health care system in terms of economics to create specialized centers for specific conditions.

Mansky: Oncologic care is one of the major fields if it comes to centralization. Many medical specialties require interdisciplinary teams for the increasingly complex oncologic treatment in their certification requirements. They also require minimum case numbers – like e.g. EUSOMA in case of breast cancer. It has also been shown in many cases that guideline adherence is a major factor which contributes to improved long-term outcomes. The provision of the required specialists, sufficient experience in applying the latest treatments, and keeping up with the latest developments ask for sufficient minimum case numbers and for institutions which can provide all the specialties and facilities needed; i.e., centralization is needed. In oncology it is more difficult to prove volume-outcome relationships. The short-term outcome of surgical (oncologic) interventions can be measured relatively easy, and volume-outcome relationships are very well known for many procedures of this kind, like e.g. for esophageal resections. However, the overall long-term outcome as measured by 5- or 10-year survival rates is much more difficult to assess and relate to one institution only. Nevertheless, based on good arguments, there is considerable agreement among medical societies that minimum case numbers should be achieved in oncologic centers. As long-term outcome is not available for short-term political decision making due to its nature, minimum case numbers as a surrogate will be an important parameter in oncology. For the general oncologic treatment, as far as it is not directly related to certain well-investigated surgical procedures, more research should be done on volume-outcome relationships. There are studies which demonstrate an impaired outcome in case of non-adherence to guidelines. However, many of these studies do not address the question whether non-adherence is related to institutional volume. Guideline adherence and volume-outcome relationships should be investigated concomitantly, if possible.

Welsch: There is a need for centralization for advanced oncologic care including complex multimodal approaches or rare disease entities. Parameters for centralization should include a minimum number of the respective treatment modality (e.g. surgery or interventional technique) and a proven experience in the management of complications or subsequent care/follow-up. Furthermore, quality parameters, i.e. morbidity or mortality rates regarding the specific treatment, will be benchmarked for centralization.

Question 3: Centralization might also lead to longer distances for patients, longer waiting times, and reduced specialized local care. Do you foresee this danger for Germany? If so, what are your suggestions to overcome this potential drawback?

Faiss: This danger is realistic and a logical consequence of centralization in medicine. This potential drawback has to be balanced with the predominant benefits of centralization.

Lordick: It is evident that care in specialized centers may contrast the wish to receive care near to where the patients actually live. However, we need to emphasize that centralized care is needed only for a limited selection of diseases and – within the disease trajectory – for a limited number of specific interventions. Good examples are the primary curative multimodal treatments for esophageal and gastric cancer, pancreatic cancer, or hepatobiliary tract cancer where we have robust scientific evidence that much better outcomes are achieved in specialized and high-volume centers. In contrast, the chronic treatment of metastatic disease, including supportive and palliative care, needs to be organized with all its requirements close to the place where the patients actually live. It is ridiculous that today, quite often, the situation is exactly reversed. We see patients who had received a gastric or pancreatic cancer resection in small peripheral hospitals with a low case load and unknown quality. Patients present at our university cancer center at the time point of recurrence, sometimes even later after previous lines of chemotherapy have failed, and we have trouble to organize specialized palliative care and hospice service for them as well as the necessary support for their families at the place where they live. This is an example of medicine in a post-rational era, driven by nebulous intentions and false incentives.

Mansky: In general, Germany is not a very ‘rural’ country if e.g. compared to large areas of the USA or Canada. Many low-volume hospitals are located in urban areas. Longer distances are not an issue in this case. In Germany, for example, one quarter of all hospitals doing this procedure perform three or less pancreatic resections per year. Volume-outcome relationships are well known for this operation. It is very hard to find any argument why such low volumes should be provided by hospitals in urban areas, where high-volume providers are available around the corner. Even in more rural areas there are no good arguments for such approaches in case of elective procedures. Public opinion surveys have shown that patients are willing to accept longer distances if this leads to improved quality. Waiting times are not a major issue in Germany. We have an oversupply of hospital services, and due to the DRG (diagnosis-related groups) incentives hospitals are willing to treat the patients. In the case of low-volume providers, this may be seen as an unwanted effect of the system. In the case of high-volume providers, these incentives would even support centralization. Discussions about possible problems of centralization are undoubtedly justified. However, we have to be aware that such arguments may also be misused for defending outdated structures.

Welsch: Centralization for complex oncologic cases will diminish the number of centers where these treatments are offered at a top level. However, I do not see a significant and relevant increase in waiting time or travel in Germany due to the relatively small country with a well-developed public transport system (maximum travel time within 5–6 h). A step-down approach of the required care level will ensure that patients will not need to come to the oncologic centers for each outpatient visit.

Question 4: What is your opinion on volume-quality correlation? How would you measure quality in oncologic visceral medicine?

Faiss: As mentioned above, reliable measurement of quality is rather difficult in medicine and especially in oncologic care. Case load, volume-quality correlation, and outcome parameters like tumor-free survival without complications are potential parameters for this measurement.

Lordick: Scientifically, the correlation of hospital volume and outcomes is proven for the primary curative treatment of esophagogastric and pancreatobiliary cancers. In addition, the implementation of quality control mechanisms has shown to reduce treatment-associated complications and mortality and to improve survival outcomes. Therefore, it is in the interest of patients to be treated in specialized centers. Also, regarding health economics, there is no alternative to the implementation of quality control and to the creation of specialized high-volume centers.

The German Cancer Society has implemented a unique catalogue of criteria to monitor centers for their quality of cancer care. This system is self-learning, flexible for the integration of new scientific evidence, and arranged by the medical community itself. Of note, this quality control system is not slipped over by any authorities, like in some other countries. My conclusion is that we have the tools for measuring quality in visceral medicine in our hands and that we have started to use them and can further elaborate on them. In my personal opinion, quality control for surgical oncology is in a better shape than for medical oncology. Much work needs to be done to strengthen quality-controlled drug therapy in visceral oncology.

Mansky: Volume-outcome relationships have been sufficiently proven for many complex procedures. Overall, there are undoubtedly positive effects of centralization for such procedures. However, the degree of volume dependency, i.e. the steepness of the regression line, is different. Thus, the effect of centralization which could, for example, be measured in terms of ‘saved lives’ is different, too. The positive effect of centralization must therefore be discussed for every disease [1]. Furthermore, the relation is statistical. Not every high-volume unit must necessarily be better than average. Centralization will exert a pressure for more transparency on high-volume centers. Funnel plots as one possible instrument to indicate the relative position of a center may become more important in the future. The Association of Coloproctology of Great Brit-

ain and Ireland gives an example how such publications may look like (www.acpgbi.org.uk/surgeon-outcomes).

Regarding quality measurement in oncology, I have given my opinion in the answer to question 2.

Welsch: There is overwhelming evidence that high-volume surgical oncology centers achieve improved patient survival as well as less mortality, less morbidity, and shorter hospital stay duration in complex cases such as in the management of pancreatic, esophageal, liver, gastric, or colorectal cancer. However, centralization results in an accumulation of complicated cases and multi-morbid patients in high-volume centers, which logically have higher post-operative morbidity rates compared with smaller hospitals treating mostly non-complicated cases. Therefore, valid quality parameters for oncologic visceral medicine should be a combined measure calculated from the variables volume, morbidity/mortality in relation to disease complexity/patient morbidity (e.g. CMI), and survival data.

Question 5: Centralization results in a limited spectrum of procedures in most peripheral hospitals. This may well lead to problems in the staffing of leading positions in regional hospitals. Do you see this problem and what is your opinion on this topic?

Faiss: Yes, this is a potential problem for regional hospitals which cannot provide specialized medicine in general. These hospitals have to work as ‘local hospitals’, referring specialized patients to ‘central hospitals’ for adequate diagnostic and therapy.

Lordick: Another way of looking at this is that due to the limited case load in most institutions, there are not enough attractive permanent positions for specialists, leading to migration of highly qualified doctors into settings where they cannot (and should not) perform the medicine they have been trained for. I have doubts if this is an effective way of organizing medicine. I rather believe that we need specialists for complex procedures which are offered in high-volume centers but at the same time other specialists for medicine close to home, where patient- and family-centered care can be delivered at a high quality. We should probably call the current definition of ‘leadership’ into question. Is a professor who was trained to treat acute leukemia and perform a bone marrow transplant, has published 150 PubMed-listed articles in 15 years, and raised funds for animal experiments naturally the best-trained person to lead a community-based oncology department where she or he needs to take care of patients with metastatic pancreatic cancer, cachexia, and psychosocial care needs? I doubt it.

Mansky: ‘Form follows function’ is a successful postulate of modern architecture. An outstanding incarnation of this principle and its effect on quality can be found in Scharoun’s Berlin Philharmonic concert hall. In analogy, in a medicine health system, structures

should follow the development of medicine and not vice versa. In Germany, we have an oversupply of hospitals. Due to historic reasons on the one hand and due to the development of medicine (increasing complexity and specialization) on the other hand, we have too many small, unspecialized hospitals. Many of these can be found in urbanized areas. The long-term viability especially of these hospitals is questionable for many reasons. If such hospitals have problems, it will not help if they perform, for example, two pancreatic resections per year. Rather vice versa: It increases the viability of these hospitals if they focus and specialize on those services which they can deliver with high quality considering their limited resources. Many hospitals have strived to do so after the introduction of DRG. Those which did not are probably too late now. Responsible physicians would also head into this direction. Even if the physician himself is able to perform complex procedures, these hospitals do not have the resources and teams for appropriate complication management. 'Failure to rescue' problems arise from this situation.

The problems of these hospitals are manifold: (i) Due to the specialization of medical education the generalists needed for the surgical and medical departments of such hospitals will hardly be available any more in the future; (ii) the physician shortage will increase this problem; (iii) the provision of increasingly costly techniques, services, and equipment for complex medical services cannot be reasonably financed for low case numbers (and there is even no need to finance it if such services are available in centers 'around the corner'); (iv) the work-life balance is also impaired in such hospitals for the younger generation of physicians as night and weekend duties are extensive; (v) it is questionable if young physicians who recognize these and other problems can be attracted to a job in such hospitals. It is easy to see that a limited spectrum of procedures will not be the major problem in their decision making.

In the case of remote regional hospitals some of these problems have to be solved. For complex elective procedures, however, referrals to centers will become more important. A 'leading physician' in such hospitals must see himself/herself (i) as a specialist in delivering those services which can be delivered at this level with the highest possible quality and (ii) as a highly responsible case manager for those services which require referrals. I cannot see why this should not be an attractive position in those smaller regional hospitals which are required for a meaningful health system structure. For the other hospitals it should be repeated that structures must and will sooner or later follow medical needs, even if resistance to change may delay necessary changes.

Welsch: Problems in the staffing of leading positions can be minimized by the implementation of cooperation models where the physician staff of a high-volume center and 1–3 peripheral hospitals is integrated into a rotation schedule during surgical or medical training. Moreover, the cooperation model saves resources (e.g. operation capacity, intensive care unit, interventional radiology) at both sites and can lead to a win-win situation. Cooperation models have been successfully developed in Heidelberg, but are well-practiced elsewhere.

Question 6: Pay for performance (P4P) is one of the key issues in centralization and specialization. What are your thoughts on this?

Faiss: In my opinion, P4P is dangerous for the health system reimbursement. Monetary optimization of P4P will lead to patient selection with the consequence that 'low-risk patients' will only be treated in non-specialized units and 'high-risk patients' will be referred to specialized institutions as defined by centralization. In consequence of this, complication rates and outcome parameters become worse in the specialized hospital, leading to negative financial effects for the specialized institutions triggered by the reimbursement system itself. This is not a favorable approach in order to optimize quality in human medicine.

Lordick: If you follow the philosophy that money is the major driver for health care providers to deliver good care, the P4P principle is probably the way to go. However, I feel that non-material incentives should not be forgotten and should be strengthened in the way how we perform medicine and how we teach the following generation. Medicine is more than business and should not be dominated by money alone although remuneration mechanisms may complement what we deem right. However, to the best of my knowledge, there is no consensus yet on optimal models of P4P, and there is no proof yet that this economically driven approach will eventually improve quality of care and patient outcomes.

Mansky: The question itself is interesting because it is not neutral. P4P can only be a 'key issue in centralization and specialization' if one supposes that performance is related to volume. Whether intended or not, the authors of the question seem to take this for granted. However, there is a more complex relationship between P4P (or value-based purchasing (VBP)) and volume. If many hospitals are investigated on an aggregated (e.g. national) level, volume-outcome relationships are easy to demonstrate in many cases. In the case of a single very-low- to low-volume hospital, however, quality often cannot be measured even if meaningful and well-adjusted quality indicators were available. The statistical uncertainties (i.e. confidence interval) in case of low case numbers are so high that it is hard to say if the hospital performs worse or better than average. The hospital cannot prove that it is 'good', whereas others cannot prove that it is 'bad'. In its 'Value-Based Purchasing Program', Medicare takes this problem into consideration. In case of very low volumes, the VBP indicators are not calculated. Thus, the question arises how to deal with low-volume providers in the case of P4P? Should they get the average price because nothing can be proven? Should they get deductions because there is general evidence that their quality is impaired on average? (Legally this would not be feasible.) It seems that P4P is a method to deal with quality differences concerning providers which deliver sufficient volumes. The low-volume problem will require a more intense reassessment and probably an extension of minimum case numbers. Thus, P4P and minimum case numbers are complementary issues.

Welsch: P4P systems rely on validated quality parameters. Otherwise there is the risk that patients are selected according to their risk in order to optimize reimbursement. Implementation of P4P

must not lead to a limitation of patient access to high-quality medical centers because of the higher costs. If these issues are controlled, P4P may further improve the quality of care.

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