

# Telemedical Methods in Otorhinology



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## ABSTRACT

Telemedicine is an umbrella term that includes all procedures supported by communication technology providing healthcare services over spatial distances. This rapidly developing area of medicine bears interesting options, especially for the field of otorhinology that is relevantly based on endoscopy and microscopy. For clinical examinations of ear, nose, pharynx, and larynx, but also for postoperative follow-up and care after head and neck cancer, data on telemedical procedures are available as well as on audiological measurements after cochlea implantation. Some of these data provide an interesting potential, sometimes they also indicate problems in cases of uncritical application of telemedicine. Its success depends decisively on the training and experience of the examiner on site. The present article gives a summarizing overview about the most significant knowledge of this rapidly developing research field.

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## ABBREVIATIONS

AGnES	Arztentlastende, gemeindenaher, E-Health-gestützte, systemische Intervention (E-Health promoted, doctor relieving, systemic intervention close to the municipality)
AFHCAN	Alaska Federal Health Care Access Network
ICC	Intraclass correlation coefficient
IT	Information technology
MBO	Muster-Berufsordnung für Ärzte (Rules of professional practice for physicians)
MRS	A Multi-resistant Staphylococcus aureus
OR	Odds ratio
RFDS	Royal flying doctor service
VERAH	Versorgungsassistentin in der Hausarztpraxis (care assistant in family practice)
95% CI	95% confidence interval

## 1. Introduction and Methodological Notes

To prepare this review article about the evidence situation regarding telemedical methods in different areas of otorhinolaryngology, a systematic literature research was performed on www.pubmed.com, applying the keywords of “telemedicine”, “e-health”, and “telehealth”, each combined with terms for the single organs and the most frequently occurring diagnoses of the discipline. Abstracts were screened and in cases of relevant data, the full text was evaluated. Numerous publications showed especially older articles from journals that are not pubmed-listed. Based on single case decisions, the full text was analyzed as well if it was available.

The assessment of the situation was completed by studies of legal dictionaries and websites on this topic such as juris.de, and of comments in the context of currently published, web-based texts, in particular on resolutions of the German Medical Assembly (Deutscher Ärztetag).

Due to the heterogeneity of the retrieved literature sources, the present article cannot claim completeness, already for methodological reasons. In order to achieve a possibly objective description, involved people are not specifically mentioned. Instead, relevant organizational characteristics of the mentioned telemedicine networks are placed in the focus in order to improve the comparability.

After elucidating the different definitions of “telemedicine”, the historical development and the economic significance will be described for better understanding. Since the implementation of telemedical methods in otorhinolaryngology is very heterogenic, first, factors fostering or impeding the development of respective networks will be presented including legal conditions. Afterwards, the study situation, classified into organs and the most frequent diagnoses will be presented and discussed.

## 2. Definition

According to the definition of the German Medical Association (Bundesärztekammer), telemedicine is an umbrella term for different medical concepts of healthcare provision that have in common the general approach to provide medical healthcare service in the areas of diagnostics, therapy, and rehabilitation as well as to support decision making over spatial (or temporal) distances. Hereby, information and communication technologies are applied [1, 2] (► **Infobox 1**). The beginnings of telemedicine are based on the worldwide problem to assure adequate access to services of the healthcare system to possibly all people. For the USA, the Institute of Medicine [3] defined telemedicine as “the use of electronic information and communication technologies to provide and support healthcare when distance separates the participants”. The use of phone and fax alone, e. g. in the context of accounting by Medicaid, is not included in the term of telemedicine.

Historically, the geographical distance is in the focus as well as obstacles such as seafaring [4–6], aviation, and aerospace [7], and thus barriers between physician and patient or between general practitioner and specialists that have to be overcome. So it is not surprising that telemedicine had its origin in Australia because of the long distances, and later further impulses came from Alaska.

Telemedicine is an umbrella term for various medical healthcare concepts that have in common the general approach that medical services of the population's healthcare in the field of diagnostic, therapy, and rehabilitation as well as medical decision making support over spatial (or temporal) distances are provided. For this purpose, information and communication technologies are applied.

► **Infobox 1** Definition of telemedicine by the German Medical Association [2].

### 3. Historical Origins of Telemedicine

In 1928, Reverend John Flynn from the Presbyterian Church founded the Aerial Medical Service with the objective to improve healthcare in the Australian outback (<https://www.flyingdoctor.org.au/>). Up to that time, only two physicians were responsible for this area of several millions of square kilometers. Accordingly, the Australian farmers as well as the Alaskan inhabitants at that time primarily provided care by means of natural remedies. Because of the deep cultural gap between the aborigines and the immigrants, the level to which shamanism was accepted was clearly lower in Australia than in Alaska.

Because of its military significance during the Second World War, nurses were deployed in 14 military bases in Alaska. After the end of the war, they remained in the cities and hence already improved the medical healthcare situation [8]. Moreover, since 1945, a mobile examination unit was created, installed in a discarded military truck. For the first time, there was then the possibility to reach inaccessible and rural areas with medical equipment. This measure was completed since 1946 by a medically equipped ship that provided healthcare in coastal settlements by sea. With developing industrialization, the construction of railways, and the development of larger settlements, these mobile units were complemented by another ship and units on trains until the 1950ies.

In Australia, the first steps were the foundations of bush hospitals, but even those could not solve the problem of the enormous distances. Furthermore, the climate impeded the exploitation of the country and thus the construction of streets. With this background, Reverend John Flynn focused on airplanes that became more reliable due to the technical developments of the Second World War to transport medical staff [9].

On May 15, 1928, the first airport base was opened in Cloncurry (Queensland) [10]. Further bases followed in Charters Towers and Charleville, later in Alice Springs (in 1939), and then also in South Australia (Port Augusta and Adelaide) and the Northern Territory (Yulara). In 1942, the service changed its name to Flying Doctor Service, since 1955 it was called Royal Flying Doctor Service (RFDS; shortly: The Flying Doctors). Up to now, the farmers on site are obliged to clean the runway (mostly a sector of the street near the farm) from plants and stones so the landing of the RFDS is always possible without risk.

At the same time, in Alaska as well as in Australia, the development of telecommunication devices was necessary in order to be able to call medical support and advice. In Alaska, first, conventional telegraphy was used, then also radio devices. In Australia, the improvement of medical healthcare was closely related to the development of a radio network that was independent from electric current. In a radius of more than 500 km, the farmers could contact a central base by means of pedal drive. So, in this way, also the era of telemedical consultation in Australia had its beginning. Boxes with emergency drugs were and are stored until today with inhabitants of the outback. Their contents is used after consultation with the RFDS. Currently, 2,338 of such boxes are distributed in the entire outback and help reducing the delay until qualified staff arrives. Based on a standardized body scheme the type and location of complaints is communicated to the central via radio that recommends suitable drugs, if needed, according to a numeric labeling.

Overall, the RFDS currently covers an area of about 7.69 million km<sup>2</sup>, which corresponds to approximately two third of the total surface of Australia (<https://www.flyingdoctor.org.au/about-the-rfds/>). The base in Alice Springs alone is responsible for an area of 1.25 million km<sup>2</sup> with a radius of 600 km where about 16,000 people live. About 26 million air kilometers arise per year; and for example in 2016/2017, nearly 37,000 Australians were transported. Until today, the RFDS is an important element of the Australian healthcare service and has its established and acknowledged position. This significance is emphasized by the fact that a picture of the founder of the RFDS is shown on the Australian 20 Dollar banknote, beside airplane and radio device.

Because of different, also economic developments in Alaska, however, the need far from large settlements decreased significantly in the 1960–1990ies so that the mobile units were discarded. But during the economic recession, problems became obvious, in particular regarding the abuse of substances and in the field of psychiatry. This insight supported a change in the direction of telemedicine. It was no longer the question of bringing the physician to a patient, but to put both in contact in order to avoid unnecessary travelling.

This led to the foundation of the Alaska Federal Health Care Access Network (AFHCAN). It is a tribal organization that connects more than 200 different bases via telemedicine. It exists since 2001 [11]. For a long time, the particular problem in Alaska was the limited data transmission rate. Thus initially stored texts, images, and datasets were transmitted. Only in the last few years, the spectrum of services could be extended by live video conferences that are available in a safe and coded way. Currently, the network handles about 3,000 cases per year, about 2/3 of them are answered on the same day, 50% even within 1 h. About one quarter of the questions concern specialists, 75% are referred to general practitioners. Regarding otorhinolaryngology, data are available from Alaska showing that the waiting time could be significantly reduced due to the introduction of telemedicine. Formerly, 47% of the patients had to wait for 5 months or longer to get an appointment with an otorhinolaryngologist, whereas this rate was first reduced to 8% due to telemedicine and meanwhile it amounted to 3% [12]. Due to an integrated video otoscope, telemedicine is also applied for planning ear interventions and for otologic follow-up examinations [13, 14], but it is increasingly used also for other ENT-related issues [15]. In this way, it is no longer necessary for 75% of the patients to travel in order to present to an ENT specialist, and 25% of the scheduled presentations to a general practitioner could be avoided.

The improved integration of these very rural areas showed the significant difference in healthcare compared to large cities. Not only the access to medical help is more difficult in rural areas, but chronic diseases are more frequently observed in remote regions. Here, Alaska was a pioneer with its mental health programs in order to draw the general attention on the sequelae of isolation in inhospitable areas.

Technical development of the insights gained in this way meanwhile allows the real-time analysis of healthcare data of astronauts in space since the beginning of the space shuttle era of the NASA [7].

## 4. National and International Reception of Telemedical Developments

With the background of the above-mentioned technical developments, telemedicine presents itself worldwide as an option to improve problems of healthcare provision in rural areas, in particular in the developing regions of Africa and Asia [16].

Bearing in mind this fact, the World Medical Association considered telemedicine as a possibility to avoid patient transportation in 2006 [16]. Already in the following year, the requirements for telemedicine were stated more precisely by the World Medical Association [17]. Even if the title of this publication suggests an ethical dimension, for the first time relevant content-related aspects were defined. In addition, a first definition of telemedicine was provided as a technique to execute medicine via spatial distances and to perform interventions, diagnostic procedures, and treatment decisions. At that time, the World Medical Association considered telemedicine primarily as a situation in which physicians and patients know each other already from a former personal contact. However, already then the obligation to detailed documentation and data safety was determined, as well as the possibility of mutual identification and possible interaction of the involved subjects, the necessity to inform the patient, to perform quality control, cost efficiency, and evidence-based processing. Accordingly, this document is still valid today. The World Medical Association explicitly stated that telemedical techniques should always be oriented at the local circumstances in order to take into account the heterogenic needs on an international scale.

In 2010, based on this definition, the German Medical Association defined guidelines for Germany [18] in order to accompany and medically control the rapidly progressing developments in the field of telemedicine. The resolution on first preconditions for good telemedicine was decided at the occasion of the 113<sup>th</sup> German Medical Assembly. With the background of many project-based island solutions, it claims an added value in healthcare provision and addressed telemonitoring of patients with chronic diseases in order to improve the quality of healthcare provision. By means of measuring the same parameters (e. g. morning weight in cases of known heart failure), telemonitoring serves for early identification and intervention (e. g. by inviting the patient to take additional medication, in this case for example furosemide) aiming at avoiding hospitalization. Investigations in different disciplines reveal that patients welcome this type of close supervision because inpatient stays and doctor's visits may be avoided [19, 20]. So already in 2010, telemedicine was considered as useful option to overcome spatial distances by means of teleconsultations also in Germany. The implementation of networks for early detection and treatment of stroke may be considered as prime example [21–24]. In the same document, first requirements regarding the quality of telemedicine were stated with a clear vote against physician-replacing, i. e. substitutive processes.

## 5. Basic Conditions For The General Application of Telemedical Measures

Especially at the beginnings of telemedicine, physicians, therapists of other healthcare professions, and patients refused the accep-

ance. So there were reservations against the reliability of telemedicine in comparison with conventional physician-patient contact. Hereby, also according to the German Medical Association [18], telemedicine and conventional medicine are not conflicting concepts, but rather complement each other. Telemedical applications are intended to support medical action with preservation of equal quality and documentation standards.

Initially, the application of telemedical procedures was only recommended if conventional methods were not available because of specific requirements in the individual case (e. g. qualification of the staff members or technical equipment), the circumstances on site (e. g. spatial distance), or the time to perform the service. Also for telemedical healthcare, the general principle of specialist standard has to be observed. Thus, quality-ensuring measures have to be applied as well.

Furthermore, the application of telemedicine requires prior acquaintance of the physician and patient. Moreover, it is necessary that they are sufficiently used to handling current technical devices such as smartphones, tablets or computers, or medical products, and have the certainty to focus on the actual topic of healthcare provision. Physicians have to have enough special expertise for medical issues as well as skills for medical procedures. They should dispose of knowledge about technical and content-related processes including possible complications, but also documentation. In the context of teleconsultation, i. e. communication from physician to physician, the invited consulting specialist should have sufficient knowledge about the equipment and working conditions of the local colleague in order to provide useful and applicable support.

Prior to each telemedical treatment, the patients have to be informed in detail, especially about possible disadvantages of a merely telemedical examination so that they might agree/disagree. This has to be observed in particular if alternatively a personal consultation is generally possible. Patients should be enabled to outweigh the probable additional burden in relation to the uncertainty because of the limits of telemedical methods. Furthermore, the patients' agreement is also required under the aspect of data protection for the storage of data and their transmission, evaluation, and documentation.

## 6. Telemedical Terminology

Because of the rapid development of telemedicine during the last years, a standardized and clear terminology (taxonomy) is missing, even if different authors [25, 26] – among them also the German Medical Association [2] with the task force “Telemedicine” – have tried to establish a classification in 2015.

The former term of “eCare” used by the German Medical Association did not prevail, today the terms of “telemedicine” or “eHealth” are applied. Originally, eHealth had been defined as umbrella term for all technological procedures with the background of healthcare issues. Telemedicine is mentioned as one application field [27] of eHealth and delineated from similar technologies that are applied for example for research or administrative purposes [2].

Generally, telemedical measures cannot be differentiated according to the temporal type of data transmission, the people involved, the type of patients' presentation, and neither to the functionality, the mode of application, and the technology. Because of the

heterogeneity and the rapid change, the topic of technology will not be dealt with in this article. However, the significance of data protection and data quality for a reliable and safe transmission has to be emphasized. ► **Infobox 2** gives an overview about the relevant taxonomic terms so that the characteristic examples described in the following may be correctly classified and compared to own interpretations.

In accordance with the development also after 2015, different applications are delimited against each other. The most frequent applications are tediagnosis, teleconsultation, telemonitoring, and teletherapy. Since they may occur generally in every medical discipline and also touch other disciplines, the task force “Telemedicine” of the German Medical Association argued already in 2015 for the use of the term of “telemedical measures” instead of “telemedicine”. This should avoid the impression of a developing, independent medical field [2].

In the context of profession-related political discussions about telemedical methods, the difference was made in the area of the involved subjects if telemedically connected physicians work in the same field, i. e. both specialized in the same discipline as for example otorhinolaryngology, or if one of them had another qualification, e. g. if a general practitioner performs ENT-specific examinations and transmits findings to an ENT colleague.

## 7. Economic Aspects of Telemedicine

Telemedicine is a booming market that is highly attractive due to the rapid developments, also from an economic point of view. More and more data contribute to this effect that confirm cost efficiency and economic potential of telemedical measures compared to traditional procedures [28]. In the USA, they increasingly lead to the fact that the (federal) state bears the expenses for telemedical services. So since 2018, as 49<sup>th</sup> federal state of the USA, Illinois re-compensates the costs for telemedical services in form of live videos in the context of Medicaid. Fifteen federal states pay for delayed recording and transmission of data, 20 states finance telemonitoring of patients and further 9 federal states bear the expenses of all three technical procedures. In addition, 32 federal states offer reimbursement for transmission fees or device charges (multiple entries are allowed) [29]. The suggested cost coverage in the USA not only for Medicaid (assumption of costs for children organized based on the federal states), but also for Medicare (remuneration for adult patients organized by the government) is currently discussed – a decision is awaited for in 2019 [30].

Such developments contribute to the fact, that the worldwide growth rate for the telemedical market is estimated to 27.5% per year until 2021 [31]. Hereby, the USA have the largest economic significance, followed by Europe and Asia.

### Type of application:

- Telediagnosis: transmission of examinations for diagnosis
- Teleconsultancy: communication between physicians, mostly general practitioners with specialists
- Teleconsultation: communication between patients and physicians
- Telemonitoring: repeated transmission of results arising from the same examination / device
- Teletherapy: therapeutic intervention via telemedical contact

### Time dimension:

- Delayed/asynchronous: transmission of stored data
- Simultaneous/live: real-time connection (e.g. video conference)

### Involved subjects:

- Physician-physician: teleconsultancy or for physicians' education and training
  - different disciplines/same disciplines
- Physician-patient: teleconsultation, e.g. in order to avoid travelling for follow-up examinations
- Patient-patient: exchange of experiences and information, e.g. in the context of self-help groups

### Location of service:

- Connection to the patients' location (home, school, institution)
- Patients come to a telemedical examination center (e.g. home-near practice, hospital, or school)

► **Infobox 2** Taxonomy of telemedical measures (modified according to [2, 25–27]).

Outside the USA, financing of telemedical networks does not keep the pace with technical developments [32]. The telemedical applications that are currently supported by the German health insurances based on selective agreements and model projects are mostly found in the field of telemonitoring [33]. The German law on safe digital communication and applications in healthcare (E-Health law) dated December 21, 2015, [34] promised financing of video conferences for the first time. After substantiation of the technical framework conditions [35] also the cost coverage of video consultations was decided on April 1, 2017. This means that the specialist groups mentioned in ► **Infobox 3** and thus also otorhinolaryngologists may perform video consultations as panel doctors in the context of the indications described in ► **Infobox 4**. An extension of the list of indications is already planned.

The precondition in any case is the confirmation that a certified video provider is involved in the technical transmission. The certifications are in course and may be verified under <http://www.kbv.de/html/videosprechstunde.php>.

The remuneration of video consultations consists of 2 elements [37]: The physician performing the video consultation receives a technology bonus of 4.21 Euro per consultation. The number of video consultations is limited to a total of 50 per three months. If the patients does not come personally to the office in one quarter, the physicians may receive 9.27 Euro once in case of treatment. The precondition is that the patient had presented to the office at least once in the previous two quarters and that the follow-up is performed in the same practice as the initial examination. Because of the estimated license fees for video services of about 100 Euro per quarter, the National Association of Statutory Health Insurance Physicians predicts that video consultations cover the expenses as of two patient contacts per week for panel doctors.

In summary, it can be stated that for the first time also in the German healthcare provision the billing of telemedical services is possible for system. If the implementation of video consultations as care instrument of an ENT panel doctor is economically reasonable, has to be decided individually. The result of every cost-benefit analysis will depend on one hand on the local acceptance, on the other and on the development of the expenses regarding certified video providers, the expenses for purchasing and maintaining the infrastructure for video consultations, and the local competitive situation. The fact that the neighbor specialist group of maxillofacial surgeons has also been approved for performing video consultations, might intensify competition even in the digital sector.

## 8. Basic Conditions For The Useful Application of Telemedical Technologies

From an economic point of view, frequently the implementation of telemedical methods is justified by possibly avoiding travel expenses. But this is only one reason for the appropriate application of this modern technology.

Advantages of telemedicine are often seen for rural regions [38, 39], in particular poorly developed areas of the world where the number of practitioners is low due to economic reasons [39]. Several investigations are available for war veterans [40] because a higher age of life or associated comorbidities make it attractive to avoid traveling to see a doctor. Hereby, also financing of medi-

cal examinations plays a role. Since for example in the USA the Veteran Affairs have to pay the travel expenses of the patients, an incentive is given to avoid traveling [40]. In this way, 145 miles and 142 min per presentation or \$18,555 could be saved per year. Disciplines that require a high amount of physician-patient interaction were considered as particularly suitable for telemedicine [41]. It must be taken into account that less traveling does not only relieve the patients (or public financiers in cases of reimbursement), but also reduces environmental pollution for example due to less carbon dioxide emissions.

- General practitioners
- Pediatricians
- Anesthesiologists
- Ophthalmologists
- Surgeons
- Otorhinolaryngologists
- Maxillofacial surgeons
- Neurologists and neurosurgeons
- Orthopedists
- Gynecologists
- Dermatologists
- Specialists for internal medicine
- Psychiatrists
- Urologists
- Phoniatrists and pedaudiologists
- Specialists for physical and rehabilitative medicine
- Radiotherapists

► **Infobox 3** German specialist groups who are allowed to perform video consultations and to charge for them (status of September 2018) [36].

Video consultations may be performed at the following occasions:

- Visual postoperative control of surgery wounds
- Visual follow-up of dermatosis, also after radiotherapeutic treatment
- Visual follow-up of acute chronic and/or open wound (s)
- Visual assessment of movement impairments/disorders of the musculoskeletal system, also of neural origin, as follow-up
- Assessment of the voice and/or speaking and/or speech as follow-up
- Anesthesiologic postoperative follow-up

► **Infobox 4** List of indications for video consultations in Germany (status of September 2018) [36].



A comparison of telemedical technologies shows that they are mostly applied by using optic devices (endoscopes, microscopes, cameras) [41]. Hereby, the data quality of the optic devices (resolution, number of pictures per second) plays a crucial role [41].

Delayed diagnosis as well as the support of appointment planning including reminding function may be helpful to optimally use available resources.

Overcoming barriers does not only refer to spatial distances. Also the increased efforts that have to be undertaken to present patients whose transportation is rather complicated (e. g. those who are colonized by multi-resistant pathogens such as multi-resistant *Staphylococcus aureus* [MRSA], receiving intensive care or being morbidly obese, prisoners) can be reduced. The same applies for difficult access to health services for patients being confined to bed or needing intensive care (e. g. in nursing homes) for health-care provision. This gain importance with regard to the demographic change and the increasing percentage of people older than 65 years to 32% in 2060 [42]. Also people belonging to social fringe groups [43] such as American or Australian indigenous inhabitants may be better cared for in this way.

The improvement of healthcare provision [44] is possible by means of telemedical methods primarily by bridging sectoral borders (e. g. by simpler consultation of specialists) with exchange of all available information about the patients. They can contribute with reports about their complaints, local physicians may include possibly available knowledge about the patients' medical history, and the tele-consultant can share the current specific knowledge for treatment planning. This increases the transparency of service and treatment procedures (patient autonomy) and allows patients to actively participate in healthcare.

- Long distances/geographical barriers between physicians and patients (e.g. healthcare on sea, during flights, in rural regions)
- Limited mobility of the patient, e.g. bedridden, obligatory ventilation, need of intensive care, colonization with multi-resistant pathogens, extreme overweight, comorbidities, obligatory control (prisoners)
- Easier access of patients to services of the healthcare system, e.g. for socially fringe groups
- Available evidence for comparability of telemedical and conventional care
- Presence of a medical emergency situation where telemedical assessment may occur more rapidly than conventional presentation
- Outpatient character of the physician-patient contact
- Involvement of specialized centers/specialists/expensive technology
- Interdisciplinary character of a presentation
- Availability of teaching for the involved parties (physicians, medical staff) for application of telemedical methods
- Service with preservation of established quality standards, e.g. medical specialist standard
- Preservation of standard information, documentation, data protection, and data storage
- Observation of transparent legal conditions
- Scientific support of the telemedicine project

► **Infobox 5** Aspects that indicate an appropriate implementation of telemedical methods.

Because of the strictly structured procedure of telemedical services with digital availability, the evaluation of the collected data for research purposes, like especially for care research and health-care reporting for improving healthcare option, is simplified.

► **Infobox 5** summarizes all mentioned factors as checklist in order to verify a healthcare situation or a telemedical project with regard to a useful conception.

## 9. Factors Impeding the Distribution of Telemedicine

### 9.1. Legal aspects

Over and over again, the legal aspects are exhaustively discussed that might stand against the application of telemedical technology [45–47]. Because of the current development with reference to the German E-health law issued on December 21, 2015 [34], but also to current resolutions to reduce the regulations of remote treatment and because of the still missing jurisdiction, no final estimation on this issue can be given here – also due to the author's missing legal qualification. However, some problems will be discussed that might be relevant for telemedically active physicians, of course without claiming to give any kind of legal advice.

The fields that might cause problems for telemedically active physicians concern:

#### 9.1.1. Aspects of data storage

From a professionally legal point of view, diagnostic data have to be stored for at least 10 years in Germany. Since civil claims become statute-barred only after 30 years in Germany, it is recommended to archive all treatment data for this period [48]. But not only in the telemedical context, would this be an enormous challenge already because of compatibility problems in the context of further development of information technological standards. Therefore, the German E-health law [34] introduces the interoperability index called *vesta* (<https://www.vesta-gematik.de/>) in order to make the standards used in public healthcare transparent, to ensure financing of new applications, to simplify the problems for telemedicine, and to define information technological standards.

#### 9.1.2. Aspects of privacy protection

In § 203, the German Civil Law regulates the protection of private data that have been confided and made known to someone in the function of a physician. Those who unauthorizedly reveal such private "secrets" may expect imprisonment up to one year or high financial fines. On level of the European Union (EU), additionally the European Charter of Fundamental Rights and since May 25, 2018, also the European General Data Protection Regulation (EU-GDPR) have to be observed. In this context, the European GDRP is important even if it does not change much for telemedical networks because they already had to determine a data protection officer. But now, possible fines reach completely new dimensions with sums of up to 10 million Euro so that it makes sense to have legal advisors when designing telemedical networks.

### 9.1.3. Restrictions of telemedical activities

Traditionally, treatment of patients exclusively via print or communication media and not face-to-face was excluded based on the prohibition of telemedical activities, anchored in § 7 of the German professional code of conduct (Muster-Berufsordnung, MBO) for physicians. However, the explanations of the German Medical Association defined approved models of telemedical procedures more precisely [49]. They encompass seven generally possible scenarios of remote treatment in which only the physician-patient contact (model 7) with a patient who was “unknown” to the physician was classified as illicit. “Unknown” in this context was defined as follows: The physician has not performed any physical examination of the patient, has no knowledge about the patient’s history and previous findings, has no medical information about the course of the disease, and no knowledge about the patient’s social circumstances.

The 121<sup>st</sup> German Congress of Physicians in 2018 abandoned this regulation by modifying the professional code of conduct.

► **Infobox 6** shows the respective paragraph in German.

In this way, according to the explanations of the German Medical Association [50], on one hand medical consultation and treatment as face-to-face contact should generally be established as gold standard, on the other hand a support of medical activities by digital technology should be promoted.

Hence, also the telemedical care for patients who present themselves for the first time, is basically possible if further requirements of medical thoroughness and information of the patients about the advantages and disadvantages of telemedical treatment are met. This revision of the regulations partly also eliminates the contradiction between the professional code of conduct and the patients’ right to freely choose a physician as well as the possibility to offer telemedical consultation in Germany from other European countries. This modification of the professional code of conduct opens the German healthcare market for medical consultation also from outside Germany.

However, other regulations oppose to this opening in the context of therapy. Based on § 48 of the Medicines Act, the Ministry for Social Affairs of Baden-Wuerttemberg [51] considers the prescription of a medicament without “obvious” face-to-face contact bet-

#### II. Obligations vis-à-vis patients

##### § 7 Treatment principles and rules of conduct

“(4) Physicians consult and treat patient during a face-to-face contact. They may use communication media as possible support. Exclusive consultation or treatment via communication media is allowed in individual cases if it can be medically justified and the required medical thoroughness, in particular by the mode of diagnosis, consultation, treatment as well as documentation, is assured. The patient has to be informed about the particularities of consultation and treatment exclusively via communication media.”

► **Infobox 6** Statement taken from the German professional code of conduct for physicians [50].

ween physician and patient as generally forbidden. This prohibition may be revoked only in “justified exceptions”. Even after discussion of the matter in the Federal State Parliament of Baden-Wuerttemberg, this estimation has not been revised [52].

The certificate of incapacity for work is issued according to § 31 of the Federal Master Treaty for Medical Practitioners (Bundesmantelvertrag) [53] in combination with the respective guidelines of the Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA). Medical examination is needed as justification of the estimation if and how long the incapacity for work is expected. Both regulations do not mention telemedical examination so that it was interpreted as still existing barrier for telemedical treatment [51]. However, on the other side, an actually performed physical examination is not requested in the Federal Master Treaty for Medical Practitioners [54]. In § 4 of the guideline on incapacity for work, the GBA required explicitly the medical examination, however, there is no hint that it has to be performed face-to-face in person.

Thus, the revision of the MBO might lead to the analogue conclusion that – according to the increasingly better study situation with comparably reliable examination findings assessed by telemedicine and by direct patient contact on individual basis and the principle of thorough documentation – the mode of diagnosis should be irrelevant for certifying the incapacity for work. This estimation, however, is opposed by another resolution of the 121<sup>st</sup> German Medical Assembly of 2018 [55], that the certification of incapacity for work should be declined if no actual face-to-face contact between physician and patient is expected in the context of exclusively remote treatment of the respective patient. Furthermore, the service guarantee has to be observed that stipulates remote treatment exclusively by panel physicians in order to avoid competition with capital-oriented companies [56].

Only future legislation and further, more precise regulations will help to better estimate the circumstances and to increase the legal certainty of the involved parties.

### 9.1.4. Other legal aspects

In cases of treatment errors via telemedicine, several questions arise depending on the involved persons (e. g. direct contact between physician and patient, activity as tele-consultant [57]) as well as on the type of contract (e. g. statutory health insurance, private health insurance, agreements of the parties regarding the liability in the context of a project [57, 58], financing). If the telemedical network is located outside of Germany, even questions of European and international legislation may be concerned. Certainly the type and effectiveness of additionally required information about telemedical particularities of the treatment and the assurance of the thoroughness in the context of the contact with observation of medical specialist standards will provide sufficient approaches for possible legal demands in cases of litigation. Seen positively, the obligation of documentation that is already requested in the MBO, can contribute to clarify such questions, however, because of missing documentation standards it may itself be an approach to negatively assess possibly erroneous processes if the provision of digital documents (as mentioned above even 10 years after treatment) is not satisfactory.



### 9.1.5. Concluding remarks on the legal situation

Despite the opening in the MBO with the general option to perform telemedical methods, numerous interesting questions regarding civil, criminal, and occupational legislation remain unanswered that require extremely thorough planning and implementation of such physician-patient contacts. On the other hand, the mentioned aspects should not discourage the development of telemedical projects because the legal certainty for telemedicine could be significantly increased due to legal consultation with modification of the MBO and the German E-health law [34] explicitly supports the implementation of video consultations.

## 9.2. Medical and technological limits and limitations of telemedicine

The necessity to not only diagnose health problems in the context of ENT-specific examination, but also to treat them, is a broadly acknowledged limitation. For example the missing occasion to remove cerumen was confirmed as limitation of ENT-related telemedicine [59].

Furthermore, it was considered as important to retrieve additional information by palpation, especially for the examination of conspicuous abnormalities of the neck [59]. In order to solve this problem, meanwhile portable haptic systems are developed for hands and fingers that are intended to transmit the palpatory impression or ultrasound is used [60, 61].

Technical barriers exist furthermore in the context of incomplete coverage with broadband networks [62] and the missing standards in information technology.

## 9.3. Acceptance of telemedical methods and devices by the population

Another limitation is the receptiveness of the involved parties – i. e. ENT specialists, patients, and medical staff – for telemedical methods and the associated technical devices and tasks.

Already in 2009, a German survey revealed that the technical equipment for digital communication between patients and ENT physicians could be generally considered as sufficiently distributed. At that time, more than 80% had a computer with internet access (more than 90% of the younger patients up to the age of 45 years) as well as nearly 50% had mobile devices with internet access.

The current survey of 250 patients of an ENT department of a university hospital [63] with a response rate of 84.4% revealed a high interest in questions regarding telemedicine. In 2,003 evaluable datasets, a very high distribution of technical devices was found that could be used for telemedical purposes (mobile phone: 94.6%, computer with internet access: 85.1%) and compared to 2009, this is a significant increase. A comparison of the reason for presentation revealed particularly high availability of smartphones (97.8%) and computers with internet access (97.8%) for patients with nasal complaints, followed by patient with ear (94.3%; 86.4%) and neck symptoms (95.9%; 74.5%). Hereby, the age, job, and education level were confirmed as influencing factors for the use of modern communication technology.

The readiness to contact the treating ENT specialist online is seen in about half of the patients. So 51.9% of the participants confirmed their readiness to send their medication schedules prior to an appointment, and 52.3% stated that they would be happy to receive digital reports of their findings after examination. Only about

one third of the patients mentioned a potential for improvement of the physician-patient contact. This may also be explained by the methodology because only patients who were able to visit the ENT department personally were interviewed, which is not the primary target group of a telemedical network. Private patients seem to be more open to new technological possibilities, especially regarding a reminder function for appointments (odds ratio [OR]: 3.69; 95% confidence interval [95% CI]: 1.26–10.79) and the online transfer of medical information (OR: 2.14; 95% CI: 0.94–4.82). Thus, there seems to be a sufficiently high readiness in the ENT sector of patients to expand telemedical contacts.

ENT patients also use the internet to prepare their medical appointments. An investigation from 2014 revealed that about 75% of the patients consulted the internet with regard to their disease and 50% with regard to the ENT specialist to be seen (N = 79) [64].

## 9.4. Acceptance of telemedical methods among physicians

At the beginning of telemedical networks, the concern among physicians was great that substituting processes might lead to the situation that other medical staff could assume ENT specific activities. VERAH [65–70] or AGNES [65, 71–73] as well as other similar concepts were considered as possible models that might restrict the medical spectrum by connecting them with a telemedical network and shift them to the sector of general medicine. Due to the clear statement of the German Medical Association against substituting processes [18] on one hand, but also an increasing number of reports about the scope of duties of VERAH and AGNES, obstacles could be removed.

Since VERAH is primarily responsible for tasks from the area of organizational services, nursing and support with information on vaccination, prevention, follow-up examinations, and compliance, positive effects might be seen also for consultations of ENT specialists [66, 67, 70]. The implementation of this system to relieve general practitioners was rated positively by medical colleagues, treated patients, and supply assistants. However, in the context of systematic literature research, no project with direct relevance to otorhinolaryngology could be identified.

AGNES was implemented in the rural areas of Mecklenburg-Vorpommern, also in the context of a telemedical network. The telemedical methods contributed to the investigation of the drug interaction and to measurements of the intraocular pressure [72, 73]. Generally, this confirms the use of telemedical technology also in a substituting concept. However, the lack of current reports during the last 9 years allows speculating that this direction is currently not pursued.

The readiness of ENT specialists to work in a telemedical network still depends on technical and professional factors [74, 75].

Regarding the technological readiness, a survey by means of a standardized questionnaire [76] was performed with 334 ENT specialists working in private practices. Only 47% of the questionnaires could be completely evaluated; with nearly 90% of the electronic health records, the practices showed to be technologically well prepared. However, the communication with partners outside the practice occurred in an analogue way in more than 60% of the cases, e. g. via fax. Potential for improvement and possible applications were primarily seen in the area of communication with other

healthcare institutions (general practitioners, hospitals) as well as fixing and reminding of appointments.

Already in 2013, the reluctance that is probably motivated by professional politics had been discussed with regard to skepticism in 55 % of the otolaryngologists [74, 75]. In this context, the survey was performed in a network [75] that provided telemedical cooperation of general practitioners with ENT specialists in an urban environment, i. e. tele-consultation from a different discipline according to ► **Infobox 2**. Thus, the general conditions – pilot study, low obvious advantages regarding the evaluation based on factors of ► **Infobox 5**, and a relatively early development stage of ENT specific telemedicine – were too unfavorable to achieve a better result.

As it is well-known, the authorization of physicians and their accounting with the health insurances of the patients are related with the respective place of work or residence. Therefore, obstacles and barriers due to national borders, e. g. in the area of Benelux/France/Germany are a limitation to offer telemedical services despite good communication possibilities. In the USA, this barrier is even more significant since the approval of physicians is incumbent to the respective federal state so that telemedical treatment might not be reimbursed despite the same language and nationality [77].

## 10. Diseases and Indications

An overview about the manifold projects regarding telemedicine in Germany was provided by the German Telemedicine Portal that was established in the context of the E-health initiative of the Federal Ministry of Health in close cooperation with the German Medical Association. The portal provided much freely available information for interested physicians and patients or initiators of telemedicine projects. With the move and restructuring of the mentioned projects since September 2018 (<https://www.informationsportal.vesta-gematik.de>) also the discipline of otorhinolaryngology had to state a significant loss of data. The registration of projects is still voluntary. However, because of conflicts of interests regarding funding, intellectual property, and IT structures of the providers of telemedical networks, they do no longer show a complete overview of all current projects.

In order to get an impression about the suitability of telemedical procedures for the assessment of frequent ENT specific diseases, among others a retrospective investigation is available [38] that rates 62 % of all ENT specific outpatient presentations as generally suitable for telemedical consultations. Diseases of the inner and middle ear were classified as suitable for telemedicine rather than diseases of the larynx or the auricle [38]. In contrast, cases where device-related examinations are necessary were classified as inadequate for telemedicine. As a result, finally also due to the current developments in the field of tele-audiometry, a relevant percentage of patients seems to be suitable for telemedical follow-up from an ENT specific point of view. In order to clarify which patient group is mostly appropriate, the evaluation of different patient cohorts was performed.

### 10.1. Mixed patient cohorts

#### 10.1.1. Postoperative presentations

Telemedical examinations were performed mainly (up to 70 %) after head and neck surgery in a cohort encompassing 250 patients [78].

About one third of these patients showed a status after interventions of the oral cavity and the oropharynx (such as sialendoscopy or tonsillectomy), another third after neck surgeries such as interventions of the thyroid, the parotid gland, or neck dissection. 30 % of all visits were classified as clinical follow-up to discuss laboratory or histological findings. For this cohort, the visits took an average of 11 min each (0–47 min) with a waiting time for the patients of 10 min. In 95 % of the cases, the patients were satisfied with the presentation and in 88 % they stated that they wanted to undergo tele-consultation again. Criticism was mainly related to technical problems including connection failures. 46 % of the patients could avoid more than 3 h of road time, another 40 % avoided 1–3 h.

Another interesting investigation evaluated the quality of photographic wound documentation with 37 women after dermatological interventions [79]. A specificity of more than 90 % could be revealed. Different assessments of wounds showed a very high correlation (intraclass correlation coefficient [ICC]  $R = 0.806$  [95 % CI: 0.694–0.991]) for the application of the ASPSIS scale regarding the assessment of postoperative wounds [80], which indicates a good congruence of the clinical estimation. Only the diagnosis of a local erythema was comparably difficult [79]. This might be a hint to technological dependence, e. g. to light exposure. Beside other scientific trials, the data mentioned here should make clear why postoperative presentations are an acknowledged indication for video consultation (► **Infobox 4**).

#### 10.1.2. Networks of the same discipline

A relatively old investigation compared the congruence of diagnostics performed by resident otolaryngologists using live video conference or storage of the examination findings and delayed diagnosis with the gold standard – the diagnosis on site performed by an ENT specialist [81]. Hence, in 92 % of the cases (36/39) of a heterogenic list of diagnoses the resident otolaryngologist and the specialist on site came to the same conclusions. In 85 % of the cases, the tele-consultant came to the same result by means of video conference. In the context of delayed forwarding, the correlation rate decreased to 64 %. This investigation with an only limited number of cases indicates on one hand the risk of diagnosis that does not correspond to the gold standard in 7–28 % of the cases if telemedical methods are applied. Additionally, it elucidates impressively the impact of live video conference for improvement of the correct diagnosis in a relevant percentage of 20 %. Own investigations of primary laryngological findings in 250 patients confirm the deviation rate [82]. A congruence of the diagnoses performed by an ENT specialist and delayed, blinded assessment of a tele-consultant could be found in 83.1 % with a high correlation rate for according therapy proposals of 94.1 %. In the cases of deviating assessments, unnecessary surgeries (“overtreatment”) were recommended twice in the context of secondary assessment and three times the indication for surgery was not made.

A prospective investigation of 62 patients suffering from sore throat [83] reveals a mean correlation of telemedical findings on one hand and face-to-face examination on the other hand for superficial lymph node pathologies as well as palatal reddening. The area of the posterior pharynx, submandibular lymph nodes, and the size of the palatal tonsil were not sufficiently well assessed. So

it seems that these anatomical regions may not be suitable for telemedical methods.

In summary, the data from merely ENT specific telemedicine networks confirm a relatively high reliability of the diagnoses that may be optimized by device-related application of video conference systems. At the same time, significant differences regarding the quality of telemedical assessment of anatomical subunits of the ENT discipline are found that should be addressed in future studies.

### 10.1.3. Networks of other disciplines

It appears to be particularly interesting for an overall improvement of the access to ENT specific knowledge that physicians of different disciplines cooperate by means of telemedicine (interdisciplinary tele-consultations). Prospectively, 50% of the ENT specific presentations of a heterogenic cohort (N = 48) were classified as avoidable by implementing ENT specific tele-consultation [59] if previous examination by a general practitioner with live consultation by an ENT specialist had taken place. Also the average correlation of the results of tele-consultation and face-to-face contact appears to be high in the entire group with 79.2%, whereas it reveals clear weaknesses with only 60% in the subgroup of patients with neck, pharyngeal, or laryngeal problems. Unfortunately, concrete diagnoses and indications are not even mentioned in the full text. Another criticism is that skype was used for transmission because this system – at least from a German point of view – does not satisfactorily meet the requirements of data protection regarding the physician-physician communication with publication of sensitive data [59].

In this context, an older investigation mentions the learning curve that examiners from other disciplines experience. In cases of endoscopic examinations of 42 individuals (55 diagnoses), probably the learning curve of the examination technique of the general practitioner on site led to wrong diagnoses in 8 of the first 20 patients [84]. In 3 patients, wrong diagnoses were made, and in other 5 cases, no diagnosis was made at all. The diagnostic spectrum was heterogenic with complaints in the area of the ears including neuro-otology, the nose as well as sore throat, however, without laryngological questions.

Thus, the data elucidate impressively the significance of training in ENT specific examination techniques and also the risk of misdiagnosing in cases of merely telemedical assessment by other disciplines, in particular in the area of the pharynx, larynx, and neck.

## 10.2. Data from homogenous patient cohorts

In the different anatomical regions of the ENT discipline, the reliability of telemedical assessment varies relevantly as well as the study situation with regard to application of tele-diagnostics, tele-consultancy, tele-consultation, tele-monitoring, and tele-therapy. Therefore, the data of homogenous cohorts will be presented in the following.

### 10.3. Otology

The clinical gold standard in Germany for examination of the auditory canal and the tympanic membrane is the application of ear microscopy. Alternatively, mainly pediatricians and general practitioners use otoscopes. In telemedical studies, regularly a video otoscope is applied [14]. In order to verify the technical equivalence to ear microscopic findings, a prospective investigation was per-

formed. Hereby, 12 neuro-otologists assessed video otoscopic records that were assigned to seven diagnostic categories based on the gold standard of ear microscopy with audiological examinations [85]. The congruence for normal eardrums amounted to only 72%. The correlation for different pathologies varied between 48.6 and 100% [13–15, 85–88]. In cases of simultaneous, blinded assessment by an ENT specialist on site and as tele-consultation, a patient satisfaction of 96% could be achieved (N = 21 patients) [89]. Time savings regarding the duration of consultation could not be confirmed. The congruence rate for the diagnoses amounted to 95%. Technically, in all cases sufficiently high-quality imaging material could be transmitted, however, in one case audio-transmission failed.

Another trial reported about a technically satisfactory quality of the images in 87% of the patients in a network of another discipline (previous examination by a general practitioner). Diagnosis failed in 18% which led to conventional examination in the following. Overall, the congruence of conventional ear microscopy with video otoscopy between general practitioners and ENT specialists seemed to be good so that this procedure was recommended for implementation in very rural regions [90].

In this way, 3,000 patients could be screened by means of video otoscopy (smartphone-based) regarding the presence of ear diseases within 6 months by training paramedical staff in India [91]. In 54% (N = 1,619), this led to the recommendation to present to an ENT specialist; 215 patients were directly reported. In 50% of these cases, surgery was recommended. Thus, in rural areas in India that are severely undersupplied, video otoscopy seems to be a valuable technology to improve the extremely poor healthcare provision.

Based on the current study situation, video otoscopic assessment in a telemedical network should be sufficiently reliable. Accordingly, it is implemented among others as telemedically therapeutic intervention for hearing impaired children in Australia [92].

### 10.3.1. Tele-audiometric examinations

Especially in developing countries, different audiometric examinations were tested in order to improve the telemedical identification of hearing impairment [43, 93–102]. With use of a computer-assisted audiometer in comparison to double-blind, conventional audiometry, a comparative investigation revealed an accuracy of 1.3 dB for measurement values of air conduction and 1.2 dB for bone conduction [103, 104]. The high accuracy was confirmed by an American-African study [105], for which 30 adults underwent examination supported by a video conference system. A measurement difference of more than 10 dB was only found in 4% of the participants. However, the telemedical measurements took some more time (10.4 vs. 8.2 min). Further investigations confirmed the high reliability also for speech audiometry [106]. In investigations from Tadjikistan and Poland the combination of audiometric examination and two standardized questionnaires was used for early detection of hearing disorders in order to certainly identify pediatric hearing impairment [99]. Hence, tone audiometry can be reliably performed by means of telemedicine.

For telemedical and possibly automated detection of hearing disorders, different tests have been developed that can also be performed via telephone or internet [107]. So the speech-in-noise test of Smits [101] is applied among others in epidemiological exami-

nations of the UK biobank and a German version is used in the hearing module of the National Cohort [108, 109].

A comparative study on telemedical or conventional support of families with hearing impaired or deaf children [110] showed that the better rating of telemedical visits by the concerned families was associated with the expressive speech development of the children. At the same time, less expenses occurred. So the implementation of tele-audiometric procedures could significantly reduce the waiting times (from 73 – 29 days) [111]. The combination of video otoscopy and tele-audiometric procedures in Australia was estimated as being particularly effective to improve the medical care of children [112], but also of aborigines [113–116].

### 10.3.2. Cochlear implantation

Also in Germany, audiological expertise is rare. So it is interesting from a local point of view if hospitals really need to have audiologists on site for cochlear implantation or if such a specialist can also be consulted on demand via telemedicine. This question was investigated by a group from St. Petersburg that confirmed technically comparable results based on measurements directly intraoperatively after 50 cochlear implantations. During measurements in pediatric as well as adult patients (0.7–48 years), triggering of the stapedius reflexes was technically different in only one of 6 channels, with comparable results for impedance and field telemetry (IFT). Tele-audiological measurements are technically 8.6 min more rapid with equal quality (N = 50; [117]). This may be a strategy in cases of scarce audiological expertise and increasing cost pressure. The authors stated that audiological measurements at their department are meanwhile performed only by telemedicine based on these data. The general savings potential for telemedically performed audiological applications was also supported by a small case series with 8 measurements [118].

The follow-up after cochlear implantation was also conceived as “remote fitting” by developing the option based on the development of hearing aids to optimize the technical settings of CI in direct contact with the patients [119]. In this way, the speech processor may be adapted and the technical specification may be controlled. The enormous initial difficulties regarding the training of decentral partners in the network were already taken into account. This award-winning network currently encompasses 21 decentral centers that are used by 500 patients who can in this way avoid long distances to reach the centers [120].

Telemedical techniques such as “remote fitting” are currently neither mentioned in the white paper on cochlea implant provision in Germany [123], nor in the S2k guideline that is actually revised [122]. Moreover, the white paper promotes audiological follow-up to be performed primarily in the cochlea implanting institution [123].

### 10.3.3. Tinnitus

Due to the high percentage of conversation and discussion in the context of tinnitus treatment regarding diagnostics, consultation, and therapy [124], it seems to be logic to test telemedical procedures also in cases of this indication. Testing seems particularly reasonable in rural regions because of the missing availability of qualified therapists for behavioral therapy of tinnitus.

For tinnitus patients, generally the above-mentioned audiological procedures are available as screening tools. Questionnaires

on diagnostics or tinnitus [125] and important influencing factors such as depression and anxiety [126] are also available online and validated.

Regarding tinnitus therapy via internet or e-mail, a whole series of trials can be found.

A total of 117 patients with tinnitus lasting for more than 6 months were provided with a self-aid manual in a randomized way by e-mail contact. With a relevant drop-out rate of more than half of the included patients, a significant reduction of the tinnitus-associated complaints was observed.

Hence, a progressive tinnitus management was developed for patients with tinnitus, partly due to brain damage, in order to improve their condition by means of phone consultation by an audiologist and a psychologist [127]. In the non-randomized observational study, an improvement of the complaints, measured with the tinnitus handicap survey 12 and 24 weeks after therapy onset could be reported, which, however, was not significant. Since there were no technical problems and the group sizes were relatively small (N = 12/15/9), the missing significance led to starting a randomized trial with improved conditions. Improvement potential was seen in the modification of the used information material and the implementation of video conferences.

The application of telemedicine to establish the contact to other affected individuals was rated as positive for tinnitus patients [124]. The objective hereby is to avoid loneliness, isolation, and withdrawal because of the tinnitus [128]. A comparative investigation on the value of an online forum compared to internet-based behavioral therapy [129] showed that the internet-based behavioral therapy was significantly superior regarding the subjective symptoms, measured with the tinnitus handicap inventory. Earlier studies [125, 130, 131] confirmed this observation that certified a sustainability of more than 3 months. In this context, the internet-based therapy seems to be superior to conventional group therapy [132]. Recent studies [133–138] further pursue this approach and indicate that tinnitus appears to be a suitable medical condition for telemedicine.

## 10.4. Neuro-otology

In the field of neuro-otology, the general applicability of tele-consultation by means of video conference was reported based on the case report of a patient with benign paroxysmal positional vertigo [139].

However, probably because of the special equipment, studies are missing that implement networks, as announced by the German Center for Vertigo and Balance Disorders of the University of Munich [140], also telemedically in order to assess the value of second opinions retrieved in this way.

One trial from the field of tele-therapy compared the stand insecurity and unsteady gait of patients suffering from multiple sclerosis [141, 142] and undergoing conventional physiotherapy (N = 25; 2 × 40 min per week) with tele-rehabilitation consisting of exercises with an Xbox 360® console and monitoring by means of video conference (N = 25; 4 × 20 min per week). After 10 weeks of therapy, both groups revealed significant improvements, measured by means of posturography [142], that were even more relevant in the tele-therapeutic group. Also the Tinetti test for identification of the risk of falls turned out to be significantly improved

in the tele-therapeutic group [141]. Because of the differently intensive times of exercising in both groups, the trial must not be misunderstood as confirmation of the superiority of tele-therapy, but rather as a hint that also in this way an improvement of the complaints of stand and gait insecurity may be achieved. Future studies will have to clarify, to what extent the actual implementation of video conference is necessary in the selected measure and if repeated controls are perhaps sufficient to maintain the compliance.

Despite the attractive option to avoid unnecessary traveling for patients with unsteady gait, only very few trials are available on telemedical procedures. One reason might be the limited therapeutic possibilities and the missing intersectoral cooperation of general practitioners and ENT specialists. Because of its enormous prevalence, vertigo is an important field of activity also for general practitioners who are often reluctant regarding the specific services of otolaryngologists.

## 10.5. Phoniatics

### 10.5.1. Diagnostics and therapy of articulation disorders

The telemedical diagnostics of speech disorders in pediatric and adolescent patients were investigated comparatively in the context of diagnostics of speech and speaking disorders [143]. Hereby, the type and severity of articulation disorders could be reliably assessed in a technically simple setup with microphone. A supporting video conference system is desirable in order to additionally include the nonverbal level during treatment (smiling, hand movements). It is recommended that a helping person is present in the decentral examination site, also for solving possibly occurring technical problems. According to a survey in India, currently about 12% of speech therapies and diagnostics are performed telemedically, based on these experiences. From rural regions in the USA [144], telemedical implementation is reported as well.

### 10.5.2. Diagnostics and therapy of disturbed speech fluency

Telemedical therapeutic interventions were performed in particular systematically in cases of disturbed speech fluency such as stuttering [145] and scientifically accompanied. In a first pilot study encompassing 6 children, the severity of stuttering could be improved by telemedicine (from 13–36% to 2–26%) with persisting effect also six months after the end of therapy.

In the context of a pilot study with adults suffering from disturbed speech fluency (N = 16), stuttering was treated via e-mail [146]. This kind of communication was used to improve therapy objectives such as personality development, improvement of the relationship between therapist and patient, and clinical decision making.

A prospective randomized trial [147] of adults (N = 40) compared therapy of stuttering based on the Camperdown program via telemedicine with the treatment in a face-to-face contact. The Camperdown program is a therapeutic approach developed in Australia to heal stuttering [148, 149], that focuses on imitating fluent speech and in this way follows behavior therapeutic principles. Also 9 months after the end of therapy, there was no significant difference between both groups. The authors interpret this result as a hint to an equal therapeutic effectiveness using even less contact time with the patients who underwent telemedicine. These comparative data are supported by a phase-I trial (N = 10 adults)

that reported an effectiveness of a merely telemedical Camperdown program with a reduction of stuttering immediately after the end of therapy with 84% and after six months with 72% [150]. Due to these positive results, further investigations on the treatment of adolescents followed; hereby a webcam-based therapy in the home environment was used [151]. A phase-I trial in three adolescents revealed a reduction of stuttering by 83% at the end of therapy and 93% up to six months afterwards. The results were again comparable to those of a phase-I trial of the same age group with face-to-face contact [152]. However, it was classified as disadvantage that the adolescents still showed a tendency in the web-based therapy to avoid speaking situations [151]. Despite the confirmed efficiency in a phase-II trial of 14 adolescents, the problem came up again that half of the participants did not show any improvement regarding the avoidance behavior of speaking situations [153]. In addition, the study design was criticized [154], especially the technical assessment of the permanence of the therapy. Hence, despite the generally high quality and number of the studies, further studies on the sustainability and effectiveness of telemedical measures are required. Up to their availability, it could be imagined to improve the initial situation for the individual by preponing tele-therapeutic approaches, to reduce the patients' stress caused by travelling and expenses, and thus to increase the acceptance.

Already in 2005, the American Speech Language Hearing Association (ASHA) valued telemedical therapy as suitable treatment option in cases of speech disorders in order to overcome barriers such as spatial distances, missing availability of specialists, immobility of patients, and in this way to improve the service situation (according to [92]).

### 10.5.3. Treatment of dysphagia

Based on the structures existing in the context of speech therapy, meanwhile also swallowing therapies are performed via telemedicine. After first investigations in Australia with positive experiences regarding the connection of a regional hospital to a center [155] and the treatment of head and neck cancer patients, this therapeutic approach was widely distributed. The necessary reliability of assessing the swallowing act amounts to mean congruence rates (kappa = 0.636) for the penetration-aspiration rates between examiner on site and tele-consultant (average absolute difference of 1.1 points on an eight-step scale) [156]. A total of 32 patients with swallowing disorders of neurological origin or after head and neck cancer were examined. The congruence of the treatment recommendations varied between excellent 100% down to 69.3% in the 9 evaluated categories. As further development, the colleagues recommended the provision of all medical documents because during the examination only the current complaints could be transmitted via fax to the tele-consultant.

Dysphagia after treatment of head and neck cancer was assessed retrospectively in an Indian cohort; hereby the local physicians were supported by experts via video conference in the sense of tele-consultancy. In 8/26 patients, the telemedical colleagues modified the treatment which led to significant improvement of the dysphagia complaints, measured by means of the Functional Oral Intake Scale from  $1.46 \pm 0.989$  to  $3.92 \pm 1.809$  ( $p < 0.0001$ ). Regarding limitations because of a missing control group, demanding a second opi-



nion probably seems to be positive for dysphagia management. Furthermore, an asynchronous telemedical care was reported for intensified swallowing therapy of patients with head and neck cancer in the home environment [157]. It facilitates the access to therapy that might be intensified by video conferences, if needed, in order to work on specific questions.

Overall, there are numerous indications in the different fields of phoniatrics that telemedical procedures might be helpful to spread this specific knowledge for the benefit of the patients.

## 10.6. Laryngology

The beginnings of tele-diagnostics in laryngology consisted of transmitting images in respiration and phonation position that were sent and examined [158]. In 29 patients, three different examiners found identical diagnoses. There was no explicit information on blinding of the findings, however, the independent assessment was mentioned. Thus, the article confirmed the technically sufficient quality of transmission in an ENT specific network. This is remarkable because in this cohort also two patients with laryngeal cancer were included. Further indications encompassed paresis of the recurrent laryngeal nerve ( $N = 4$ ) and morphologic changes of the vocal folds that were not described in detail.

In another prospective trial [159], flexible endoscopy was recorded in 79 patients with smartphone by means of adapters. The examination was performed by a resident otolaryngologist and the assessment by an ENT specialist, i. e. physicians from the same discipline. Hereby, a congruence rate of 88.6% ( $\kappa = 0.747$  [95% CI: 0.643–0.851]) was revealed. In 12 cases, the clinical procedure was modified after re-assessment, one examination had to be repeated.

Overall, the few laryngological trials show the complexity of this part of ENT specific examination techniques, also in the context of the use of flexible nasopharyngoscopes. Hence, this section seems to be suitable for telemedicine only in networks of the same discipline and after specific training.

## 10.7. Rhinology

In comparison to other areas of otorhinolaryngology, rhinological telemedicine is clearly less developed. Telemedical approaches have been suggested for patients with chronic rhinosinusitis as strategy to reduce costs and to minimize the stress [160]. Even a software for smartphones was presented that is intended to identify nasal obstruction by analyzing the breathing sounds and that is able to differentiate between patients with nasal obstruction and patients after septoplasty [161]. However, data on clinical application are not available.

As an approach for second opinion and for research, endonasal-endoscopic video records were validated regarding two different aspects.

The reliable assessment of the endonasal anatomy with chronic polypous rhinosinusitis and measurement of the polyp size [162, 163] is possible in the context of therapy studies, in the same way as a reliable, blinded assessment of endonasal secretion [162] and edema [162, 164]. Obstruction due to septal deviation [162], however, was only reliable to a limited extent [162]. The results of the assessment of the middle turbinate were contradictory [163, 165], but they improved after specific training [165].

Furthermore, the intraoperative aspect of endonasal bleeding in the context of paranasal sinus surgery can be reliably classified in a standardized way based on video recordings [166–169]. Due to the development of 3D endoscopy, interesting new aspects seem to arise for second opinion demands [170]. In general, however, the symptom complex of nasal obstruction has not found a promising access to telemedicine.

### 10.7.1. Allergology

Also for the field of allergology, telemedical approaches exist. So the performance of a prick test with penicillin was described in the context of suspected penicillin allergy [171]. The objective was to deescalate a current antibiotic therapy. A medical-technical assistant on site performed the test in 50 included patients under telemedical monitoring by an allergologist. In 46/50 patients it was negative. Accordingly, the medication of 33 patients could be successfully changed to a beta-lactam antibiotic. The four patients with allergic reaction did not experience severe complications. Because of the risk (even if it is very low) of anaphylactic reaction during prick testing [172, 173], the performance seems to be prone to criticism in Germany. In order to meet such controversies, the American College of Allergy, Asthma & Immunology published a position paper [174] that emphasizes the safety of the telemedical treatment. For the direct physician-patient contact, an already existing relationship between the two parties is required or alternatively a live contact to establish such a relationship. If this is not possible, the allergists should assume the role of tele-consultant of a referring colleague on site. Unfortunately, also in this document the claim of sufficient financial remuneration takes broad space, which is opposite to a critical assessment of the chances and risks of telemedical methods in the context of allergic examinations and treatments.

Regarding the indication spectrum of telemedicine in allergology, a retrospective investigation confirms heterogenic indications in  $N = 112$  patients [175]. With a rate of 59% first presentations, a high percentage of patients (about 20%) in this young cohort (age:  $26.9 \pm 15.3$  years) presented with allergic rhinitis. Another indication was suspected food allergy (30%) or urticaria (16%). 19/112 patients (16.9%) were invited to personally present afterwards. Finally, there were no significant differences between the first presentation and follow-up, the number of prescriptions, and relevant savings of time (200 workdays) and costs (\$ 58,000) by telemedical methods.

Regarding tele-monitoring in allergology, a case series of 2 boys is available [176], for whom an allergy could not be clearly allotted traditionally to the complaints and the proven sensitization (in RIST and RAST). Both boys reported via smartphone about their complaints in the course by means of the Rhinoconjunctivitis Total Symptom Score (RTSS) so that at a later time these complaints could be correlated with the measured pollen load. Based on this, allergy against grass and olive pollen could be confirmed. Of course, data assessment could have been possible also by means of written complaints diaries. However, especially with regard to the patients' ages (7 and 10 years), it could be expected that the use of technical devices would increase the compliance.

Thus, allergology is a highly interesting field for innovative technological solutions. Since these patients are already used to write



symptom diaries, the implementation of medical “apps” may even be more suitable. In this context, the author refers to the respective overview in this issue.

### 10.8. Head and neck cancer

In this context, telemedical solutions have been developed to support symptom control [177], to increase the quality of life [178] of patients suffering from head and neck cancer, and to early detect neoplasms in the oral cavity [179]. According to an online survey [180], the highest need for supporting measures for patients with cancer diagnosis (N = 212) arises in the field of body care (66%), of supporting healthy lifestyle (54%), social (43%) and psychological aid (38%) as well as with regard to programs that refer to questions of life (24%). Even if the result of the survey could only summarize answers of about one tenth of the head and neck cancer patients, it indicates the factors that are associated with the search for support in a particular way. Among others, those were problems with the male gender, younger ages, treatment with chemotherapy or combined radio-chemotherapy, and low quality of life. All these are factors that occur frequently and also in combination in patients suffering from head and neck cancer.

Based on the contents of these data, a study offered psychosocial intervention via phone calls [181]. Since traditionally head and neck cancer patients can hardly be convinced from psychosocial interventions [182], it was evaluated if a positive effect may be achieved by phone call intervention up to eight times. Eight of 24 included patients interrupted the treatment, but overall an improved dealing with negative emotional and physical effects of the basic disease was observed.

For planning and deciding therapy, the consultation of certified tumor centers is recommended in Germany. Telemedical measures are established worldwide, if no sufficient expertise is available on site to assure balanced consultation [183].

In order to early detect hearing impairment based on ototoxic side effects of a cisplatin-based chemotherapy, an audiological screening tool (OtoID) was developed that recognized this impairment automatically [184] with a sensitivity of 80.6% and a specificity of 85.3%. This development is a simple approach to improve the quality of healthcare services with simultaneous reduction of side effects.

Swallowing therapy was performed as approach for tele-therapy in a randomized trial of patients with oropharyngeal carcinoma [185], either with face-to-face contact to a therapist or supported by telemedicine, or by the patients alone. Hereby, all 79 patients received definitive radio-chemotherapy. The overall therapy adherence was low with 27% and highest in the group undergoing personal therapy. The tendency was observed that telemedical therapy is superior to therapy performed independently by the patients. Since the performance of swallowing therapy supported by a therapist is very resources-consuming, the telemedical approach appears to be valuable and should be further developed. Furthermore, in this study it became obvious that an active tobacco abuse at therapy onset was a predictive factor indicating poor therapy adherence.

In summary, head and neck cancer patients seem to be difficult candidates for telemedical procedures. The majority of the trials deals with those patients during radiation therapy. Possibly, an early

offer is more helpful, also to intensify the relationship between physicians and patients, in order to provide the support desired by the patients for the benefit of both parties.

### 10.9. Palliative care

The implementation of telemedical methods was evaluated for palliative care for patients with advanced cancer disease in a prospective and randomized way [186]. The total of 74 patients included 8 cases of head and neck cancer. The trial evaluated the impact of weekly contacts by means of telemedicine over a period of 12 weeks. It reported about a higher load with symptoms because of the telemedical procedure and thus additional stress for the patients. The authors classified this deterioration as nocebo effect that enhances the complaints due to the increased awareness of physical symptoms. However, protocol deviations in the recruiting process and the relatively high drop-out rates impair the discussion of this trial. Thus, as first randomized trial of its kind, it should not lead to definitely refuse a telemedical approach [187], but rather draw the attention to problems of the study design in the context of palliative care. Furthermore, this study contradicts to a Cochrane analysis [188] that based on an evaluation of 23 trials, one of them a current investigation with telemedical functionality [189], could confirm the effectiveness for palliative care in the home environment. This data evaluation also included palliative patients with head and neck cancer.

Another trial [190] including 18 patients, two of them with head and neck cancer, could confirm positive effects. Inclusion criteria were severe functional impairments (Karnofsky index of <60%) and a predicted expectancy of life of less than 3 months. By means of the offered provision with a telemedical contact that was easily established with palliative care physicians, barriers could be reduced, the patients had the feeling of more self-determination, and video conferences also allowed non-verbal communication so that not all complaints had to be mentioned to make them even more aware. Also from the perspective of the caring staff, an improved insight into the actual home situation was possible. The patients and treating persons highly appreciated the intensified personal contact and the positive character to make appointments for further conversation.

Accordingly, a review article mentions a whole series of projects to further develop palliative care in particular for head and neck cancer patients by means of telemedical procedures [191].

### 10.10. Telemedical methods in sleep medicine

For diagnostics and therapy, especially monitoring, of sleep-related breathing disorders, numerous developments are found that are currently not yet implemented in clinical routine [192, 193]. In the context of a position paper, basic conditions for telemedical procedures were defined for the USA [194] as well as for Germany [195].

#### 10.10.1. Tele-diagnostics

Comparing conventional polygraphy with telemedical connection, the telemedical procedure could not achieve an improved quality of the diagnostics [196]. However, a high reliability was observed for the number of apneas/hypopneas (ICC: 0.94 [0.88–0.96]), the apnea-hypopnea index (ICC: 0.97 [0.95–0.98]), the duration of oxy-

gen desaturation (ICC: 0.98 [0.97–0.99]) as well as the average oxygen saturation (ICC: 0.97 [0.94–0.98]).

The combination of smartphones with an adapter for measuring the oxygen saturation and pulse [197] is well validated. Regarding the application in children [198] as well as in adults [199], data are available on the implementation as screening with similar systems. Hereby a sensitivity of the technology of 100% and a specificity of 85% could be confirmed for 15 adults.

### 10.10.2. Telemonitoring

In the field of sleep-related breathing disorder, telemedical methods are applied in particular for telemonitoring. The objective pursued is the increase of the compliance [194], in particular of ventilation therapy (continuous positive airway pressure [CPAP] or biphasic positive airway pressure [BiPAP]). The acceptance by the patients seems to be sufficient for monitoring. In an interview of 160 patients, 78% were open for monitoring, however, a relevant percentage of 40% considered this monitoring as intrusive [200].

The effects of monitoring are currently not clarified. While 78% of a German cohort were monitored 10 months after onset of ventilation therapy without achieving a positive therapeutic effect, the refusal of monitoring was associated with a higher rate of therapy interruption [200]. In this trial, monitoring did not lead to an improved average duration of application of the CPAP therapy, other studies showed that the rate of therapy interruptions could be reduced by telemonitoring [201–203], the application of therapy was increased [202–206], and the therapy efficiency [207, 208] could be improved, also by reducing the work time of the nursing health-care staff [209].

### 10.10.3. Teletherapy

Based on these monitoring data, however, therapeutic intervention is possible with an additional positive effect. A comparative German investigation of a total of 1,000 patients [210] could reveal a positive effect of telemedical care in both groups if additionally a reaction occurred when a reduction of the use of the ventilation device was observed. According to the study protocol, the participants of this group received a phone call if the ventilation device was used for less than 4 h per night during the first two weeks of therapy. This intervention led to an increased application of the device in hours per night as well as in the numbers of therapy days and a significantly lower rate of therapy interruptions. Furthermore, the incidence of mask-associated complaints could be reduced.

In summary, the development of telemedical procedures in the field of sleep medicine seems to have progressed to that extent that the integration of wishes and ideas of the individual patients in the diagnostic process as well as the monitoring of patients could be optimized to increase the compliance and to identify high-risk patients, and to improve the access to therapy and telemedical methods.

## 11. Conclusion and Outlook

The development of telemedical methods in otorhinolaryngology opens completely new approaches to question diagnostic and therapeutic procedures and to improve the evidence of our discipline by comparative investigations. The described scientific trials were

sufficient to implement remuneration of video consultations also for otorhinolaryngology. This is a chance to compete with other disciplines and to design our field in the digital era in cooperation with medical technology and companies of information technology. This will increase the attractiveness also for younger colleagues and to improve the quality of healthcare provision, especially with regard to improved availability of ENT specialists for each patient.

### Conflict of Interest

The author states that there is no conflict of interest.

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