



Master Thesis

Analysis of current factors that impede the
implementation of Quality of life measures in
medical clinics and practices

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Abstract

Analysis of current factors that impede the implementation of Quality of life measures in medical clinics and practices. *Viktor Berghaus*

The aim of this research is to identify factors that impede the implementation of patient reported outcome measures (PROM's) and health related Quality of Life (QoL) measures in medical practice. Therefore, scientific literature has been critically reviewed for impediments for PROM and QoL implementation. In addition, five interviews with medical professionals (MP's) have been conducted and revealed that most of the theoretical findings are in line with empirical observations. The interview questions were focused on impediments for PROM's and QoL measurements with regard to the awareness, categorization, strategy and skills of the MP's. The interviewed doctors who already conducted QoL measurements were experienced and familiar with the respective measurements. However, the other doctors had a rough theoretical understanding of QoL measures, but no in-depth knowledge. This is similar regarding the categorization of QoL measures: MP's that conducted QoL measurements before, knew about most relevant statistical and organizational factors and could provide examples for their successful application. Moreover, time-constraints and bureaucracy seem to be the most relevant impediments for a permanent implementation of QoL measures in Germany. Most of the MP's mentioned that their willingness to acquire skills that allow the implementation and conduction of QoL measures is rather low, mainly because they are close to retirement. Future research should focus on possibilities to introduce QoL measures in a way that is time-efficient and easy to implement. Nevertheless, extensive evaluation studies are needed to remove any ambiguity about the actual impact of PROM and QoL surveys on medical and psychosocial care.

Keywords: Patient-reported outcome, health related quality of life, well-being

Resumo

Análise dos fatores atuais que impedem a implementação de medidas de qualidade de vida em clínicas e práticas médicas. *Viktor Berghaus*

O objetivo desta pesquisa é identificar os fatores que impedem a implementação de medidas dos resultados reportados pelos pacientes (PROM's) e medidas de qualidade de vida (QoL) relacionadas com a saúde na prática médica. Portanto, a literatura científica tem sido alterada de forma crítica quanto a impedimentos à implementação de PROM's e QoL. Além disso, foram realizadas cinco entrevistas com médicos que revelaram que a maioria dos resultados teóricos está de acordo com as observações empíricas. As perguntas da entrevista foram focadas em impedimentos para medições de PROM's e QoL no que diz respeito à conscientização, categorização, estratégia e competências dos médicos. Os médicos entrevistados que já conheciam as medidas de QoL estavam já familiarizados com as respectivas medidas. No entanto, os outros médicos tinham uma compreensão teórica aproximada das medidas de QoL, mas nenhum conhecimento profundo. Além disso, as limitações de tempo e a burocracia parecem ser os impedimentos mais relevantes para uma implementação permanente das medidas de QoL na Alemanha. A maioria dos médicos mencionou que sua disposição em adquirir competências que permitem a implementação e a condução de medidas de qualidade de vida é bastante baixa, principalmente porque estão próximos da reforma. Pesquisas futuras devem concentrar-se nas possibilidades de introduzir medidas de QoL de uma maneira que seja eficiente em termos de tempo e fácil de implementar. No entanto, são necessários estudos de avaliação exaustivos para afastar qualquer ambiguidade sobre o real impacto das pesquisas de PROM's e QoL sobre a saúde.

Keywords: Resultados reportados pelo paciente, qualidade de vida relacionada com a saúde, bem-estar

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Table of Abbreviations

CT – Computer tomography

ePRO – Electronic patient reported outcome

ICHOM – International Consortium for Health Outcomes Measurement

ILO – International Labour Organisation

IPU – Integrated Practice Unit

IVR – Interactive voice response

MP – Medical professional

MRI – Magnet resonance imaging

MRT – Magnet resonance Imaging

PRO – Patient reported outcome

PROM – Patient reported outcome measurement

QoL – Quality of Life

RQ – Research question

UK – United Kingdom

US – United States

VBHC – Value based health care

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1 Introduction

According to the International Labour Organisation (ILO, 2014), health care systems all over the world are in an ongoing crisis. Market-based systems like in the US and the state system of Britain are in the same crisis of managing the balance between performance expectations and cost pressure. What these systems have in common is that they are mainly controlled via the input: how much money is spent on medicines, hospitals, and doctors? The "output" or the results of the supply, only play a minor role.

In addition, health care costs grow faster in OECD countries in comparison to the respective national gross domestic products (OECD, 2018; WEF, 2017). Still, many medical professionals, policy makers and patients would prefer a care that is based continuously on the results and proper treatment (Basch, 2017; Brim & Pearson, 2013; Deshpande et al., 2011; Hostetter & Klein, 2011). The concept of Value Based Health Care (VBHC) seems to answer these needs. The researchers Chodroff and Krivenko (1994) mentioned the term "VBHC" already in 1994. They suggested that those institutions that achieve best clinical outcomes while consuming minimal financial resources will be successful and therefore profitable. The economist Michael Porter took up the VBHC principle and expanded it. He defines value as "health outcomes per dollar spent" (Porter, 2010). In contrast to existing approaches, Porter is not concerned with offering as many medical services as possible at the lowest possible price to the population, but rather with offering the patients services that yield the best possible results while being economical. Porter explains that the standard recipe for high quality at a low price used to be competition (ICHOM, 2017b). However, simply increasing competition in the health care sector has not led to the desired successes in recent decades and has rather deteriorated overall quality. Based on the criteria of evidence-based medicine, the value-based medicine approach develops relevant assessment parameters since it hierarchizes the patient-relevant factors in a certain way and determines the value of a medical treatment not only abstractly, but with regard to the respective patient (Porter & Teisberg, 2006). The focus is on the value of an intervention, with the main goal to improve the quality of life (QoL) for the individual patient and / or to prolong the survival time. The holistic consideration of different factors and their evaluation in the context of each other ensures that it is possible to make decisions that are in the interest of overall patient well-being, especially in the case of highly complex interventions at an advanced stage of the disease. Here, the QoL, which is often poorly reflected in current studies, is very important, because for the patient, the value of an intervention is usually not measured solely on the basis of the question of whether the

statistical probability of survival changes from 60 to 90 days, but for the patient is at least equally important, with which accompanying circumstances and side effects this life extension is "bought" (Porter & Lee, 2013).

According to Porter, measuring patient-reported outcomes measures (PROM's) such as the QoL are expected to increase the value for patients in the most effective way (Porter & Lee, 2013). Hospitals that implement such measures are expected to improve their services, the well-being of patients and as a result their competitiveness and financial performance. Likewise, the whole health care system is supposed to profit from improved care. However, the implementation of PROM's in clinical practice is rare (Wagle, 2017). Thus, leaders in health care might underestimate the advantages of PROM's and their potential to improve clinical performance.

The main problem that will be addressed in this thesis is "Why are PROM's and especially QoL's rarely implemented in clinical practice?". Therefore, the functionality, benefits and limitations of PROM's with the example of the QoL measure will be introduced and reasons for the lack of implementation presented. The research questions that have been developed are:

RQ1: How familiar are medical professionals (MP's) with QoL measures?

RQ 2: How do medical professionals categorize QoL measures?

RQ 3: How do medical professionals evaluate QoL measures?

RQ 4: Are medical professionals interested in gaining skills regarding QoL measurement?

For the literature review, more than 100 scientific papers were examined in total, which provided key findings about impediments for the implementation of PROM's and QoL measures. After reviewing the current literature for functionality, benefits and limitations of PROM's / QoL measures, a survey for personal interviews was developed in order to obtain real life data. The survey was designed in order to evaluate the impact of PROM's / QoL measures and to identify factors that facilitate or impede the implementation of PROM's / QoL measures in clinical and non-clinical practice. It includes questions about awareness, the categorization of PROM's / QoL measures as well as strategies and skills that used by MP's to handle them. This way, it was tested if the findings from the literature review apply in the practical context of MP's. Moreover, questions were asked with regard to the above mentioned four main categories:

1.Awareness: In this section, the interview partners are asked if they perceive a need to measure outcomes in their organization and which measuring tools they know and which they use. This way the familiarity with the topic of outcome measurement will be determined.

2.Categorization: In this stage, the personal opinion about PROM's and QoL will be asked for. If the interviewee already made experiences with outcome measurement, questions regarding impact on processes, treatments and patients will be asked. In both cases the individual conception of outcome measurement will be detected ideally.

3. Strategies: If applicable, the interviewer will ask about the overall impact of PROM's / QoL measures on clinical practice, the way in which they are conducted and which kind of problems emerged before, after and during the implementation. If there are no experiences with PROM's and QoL measures implementation, the functionality of PROM's and QoL measures are explained first. Subsequently, the interviewees are asked about their opinion on PROM's and QoL measurements regarding potential benefits, disadvantages and impediments that might come with their implementation. In this case, the interviewees will also be asked for reasons why PROM's and QoL measures have not been implemented at their organization yet.

4. Skill development: At the end of the interview the MP's are asked whether their organization provides or can imagine providing any specific measures or funding projects to generate or enforce PROM's and QoL measures. It will also be determined if the individuals perceive a need to learn (more) about PROM's and QoL measures in order to improve clinical practice.

This thesis is structured in the following way: In the first chapter the literature will be reviewed regarding the functionality, potential and limitations of PROM's and QoL measures and reasons for their lack of implementation will be examined. The following chapter will be about the results of the interviews. The third chapter is about the methodology that was applied for this thesis and explain the way in which data was collected. The collected data will be analysed in the fourth chapter and compared with existing literature so that the main findings can be gathered. Finally, main conclusions from all the findings will be derived and suggestions for future research will be presented.

2 Literature Review

2.1 Components of VBHC

According to Porter and Lee (2013) the implementation of VBHC is based on six components:

1. Organizing providers of medical services into Integrated Practice Units (IPU's)
2. Measure outcomes and costs (value) for every patient
3. Move to bundled payments for care cycles
4. Integrate care delivery across separate facilities
5. Expand excellent services across geographically
6. Build an enabling information technology platform

As can be seen in the following graph, all the components are interrelated and have the ability to reinforce each other. For example, developing IPU's allows the organization to specialize in certain treatments or therapies. This slims down the operating areas and makes it easier to measure outcomes and costs for similar treatments. Ideally, the information technology platform supports all the requirements of the other components.

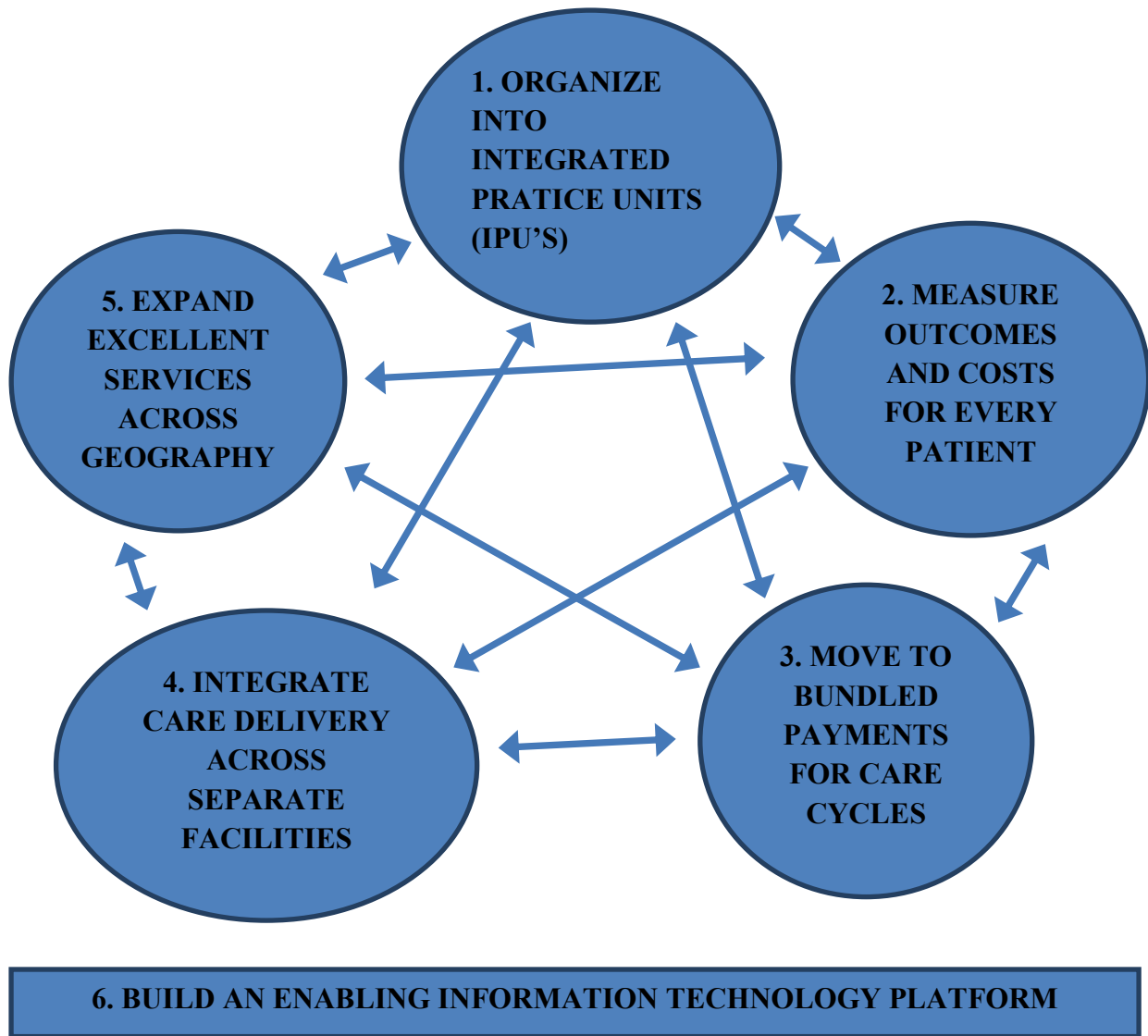


Figure 1: The six components of VBHC

Source: Porter and Lee (2013)

Porter and Lee (2013) also state that the second component (measuring outcomes and costs) is the action with the biggest potential to improve the healthcare system. This is for two reasons: First, by deciding to measure outcomes, organizations will receive direct feedback about the quality and performance of their activities. This way, underperformance can be detected and counter-measures implemented. Second, as soon as organizations publish the outcomes of their actions, these organisations are under public pressure and therefore have strong incentives to deliver good results.

A good example for this is the introduction of mandatory publication of success rates for in vitro fertilization after the implementation of the Clinic Success Rate and Certification Act in

the US in 1992. As soon as the publication became mandatory in 1997, the percentage of successful in vitro birth increased significantly for clinics with few and many procedures alike.

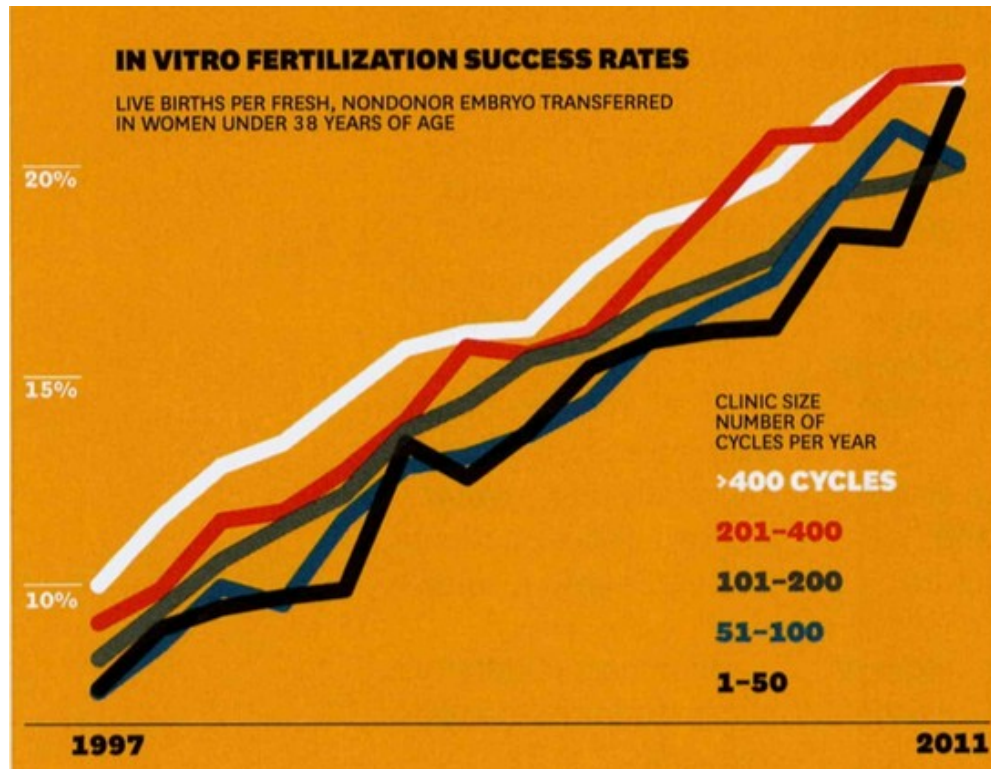


Figure 2: Success rates of in vitro fertilization in the United States of America (1997 - 2011)

Source: Porter and Lee (2013)

So far, many outcome measurements focus on the specialty of the physician (i.e. orthodontia) or the type of intervention (i.e. oral examination), but instead outcomes are supposed to be measured by medical condition (i.e. caries) (Porter & Lee, 2013). But measuring outcomes alone is not a guarantee for improving value for patients. It is critical to assess outcomes that are important for the patient as well. Thus, it is necessary to classify outcomes that are relevant for the patient into three tiers: 1. Health status achieved or retained, 2. Process of recovery and 3. Sustainability of health.

The first Tier is about examining the survival of the patient and to measure in how far the patient was able to maintain the health status or if there is a chance to reach the health status that was existent prior to the intervention. Tier 2 measures the time until recovery is completed and is meant to detect discomforts that came up during the treatment like pain during a treatment or new diseases that emerged after the intervention. The third and final tier

is intended to identify the long-term success of the intervention, which is dependent on the emergence of recurrences and long-acting consequences of therapy. This point is important for the patient as well as the provider, since both of them profit from sustainable improvements to the health status of the patient.

2.2 PROM's

2.2.1 PROM Definition

Within the last years, the desire to fully grasp the value and usability of PROM's in clinical practice grew (Basch, 2017; Brim & Pearson, 2013; Deshpande et al., 2011; Hostetter & Klein, 2011). In contrast to physician- or nurse-reported outcomes, PROM's are defined as a systematic examination of the outcomes of an intervention, based on information that was directly given from the patient (Chu et al., 2014). This way, PROM's make it possible to see the treatment from the perspective of the patient so that the QoL and functional status of the patient can be revealed (Green & Higgins, 2005; Parrish, 2010; Wiklund, 2004). PROM's are also considered to allow patients to participate in the decision making regarding the treatment and to enable them to discuss their well-being effectively (McAllister & Dearing, 2015; Schepers et al., 2014; Wintner et al., 2012). Moreover, the results from PROM's can be used to compare the effectiveness of different treatment methods and derive respective changes in policies (Chang et al., 2011; Huebner et al., 2014; Marquis et al., 2006; Talcott et al., 2014). The US Food and Drug Administration suggests using PROM's when the issue is best known by the patient or if the best measurement can be achieved through the perspective of the patient (Food & Administration, 2009).

Even though selected hospitals and physicians started to use PROMs, their usage is mainly common in England, Sweden, and some states within the United States (US) (Black, 2013). In 2009, mandatory audits were implemented in the UK for all providers of hip and knee replacement, groin hernia repair, and varicose vein surgery. However, in October 2017 the obligation to use PROM's for varicose vein surgery and groin hernia surgery was removed, since the number of surgeries for varicose veins is very low and respective afflictions for patients tend to be rare (Enston, 2017). Similarly, groin hernia surgeries tend to be mainly conducted in order to prevent from emergency surgeries, rather than to treat symptoms, that

are usually very limited. Additionally, there is a lack of condition-specific PROM for groin hernia surgeries.

2.2.2 Potential of PROM's

There are three ways in which PROM's can improve health care: helping physicians offering improved care that is mainly focused on the patient, enabling assessments and comparisons of provider quality and collecting information in order to examine procedures and strategies (Black, 2013).

2.2.2.1 Helping physicians offering improved care that is mainly focused on the patient

PROMs facilitate sound decision making for physicians as well as patients by monitoring their health status (Stiggelbout et al., 2012). For instance, surgeons can optimize the timing for operating hip osteoarthritis by measuring the condition of the patient three times a month (Evans, 2018). Likewise, both patients and providers can manage long term conditions easier when reports are developed on a regular basis (PROM2.0, 2018). Using PROM's is also considered to be important, because sometimes the preferred treatment of patients is overlooked by health care professionals (Slevin et al., 1990). Cancer patients for example, are often willing to receive a more radical treatment even when chances of success are low. There are also several studies that suggest that PROM's are a very effective tool to improve the communication between the patient and the provider (Detmar et al., 2002b; Mathias et al., 1994; Skevington et al., 2005; Street Jr et al., 1994; Taenzer et al., 2000). Up to this point, PROM's are expected to have a lot of potential when it comes to determining targets and preferences between health care professionals and patients that suffer from evolving and complex conditions (Marshall et al., 2006). Previously available studies also showed that the use of PROM instruments led to a better adaptation of the dosage of analgesics (Trowbridge et al., 1997), that the physician-patient communication improved (Detmar et al., 2002b; Taenzer et al., 2000), more topics were discussed (Detmar et al., 2002b), patients feel more emotional support and physicians tend to be more sensitive to problem areas of quality of life, which are usually underestimated (Detmar et al., 2002b). Moreover, previous studies have shown that PROM's contribute substantially in care processes like diagnosing and managing patient conditions (Espallargues et al., 2000; Greenhalgh & Meadows, 1999). Especially

mental health diseases are much more likely to be identified. Valderas et al. (2008) confirm that PROM's have been proven to enhance the diagnosis of depression in particular. Likewise, Dowrick and Buchan (1995) suggest that PROM's in the area of mental health enhance the capability of health care professionals to identify conditions during routine practice. Lewis et al. (1996) also showed that patients who participated in a self-administered computerized questionnaire for mental illnesses displayed a slight clinical improvement in comparison to a control group that did not receive such a treatment. To sum up, PROM's allow doctors to provide treatments that are very effective due to the fact that they are much more adapted to the patient.

2.2.2.2 Enabling assessments and comparisons of provider quality

Comparisons of quality between providers are expected to enhance overall quality of delivered services: outcome reports from other patients can serve as a basis when patients from the same target group are looking for optimal treatment (Coulter, 2010). Whereby, patients consider other aspects like the travel time to the hospital as well. Moreover, by reporting PROMs on a regular basis, providers assume responsibilities for their performance publicly. Ideally, information from PROMs allow physicians to prove their competencies (Coulter, 2010).

According to Porter and Teisberg (2006), outcomes have to be compared globally in order to identify best practices for interventions. Therefore, the International Consortium for Health Outcomes Measurement (ICHOM) developed international standard sets for measuring outcomes. ICHOM assumes that there are certain providers for example in developing countries that are able to conduct certain interventions faster, at a significantly lower price and with less complications in comparison to some developed countries. The standard sets make these superior treatments visible and allow other providers to use more efficient and effective techniques. So far, ICHOM developed 24 standard sets that cover 54% of the global disease burden (ICHOM, 2017a).

Since PROMs have been implemented rather recently and sparsely, they have not been used yet to compare providers' performance to an international extent (Valderas et al., 2008).

2.2.2.3 Collecting information in order to examine procedures and strategies

By taking the outcomes and volumes of provided health care services into account, the evaluation of the productivity of the provider can be augmented (Baker et al., 2012). Apart from this, the data collection allows the assessment of the medical and monetary effectiveness of certain interventions. Thus, it is possible to assess policies dealing with the implementation of innovative services or prices for certain treatments in a fast and inexpensive way (Chard et al., 2011; Neuburger et al., 2012). Randomised trials that have been conducted with PROM's in clinical practice proved that they are an effective tool to improve processes like developing diagnoses (Valderas et al., 2008).

In clinical trials, the importance of PROM data is increasingly considered important since it helps to improve the quality and completeness of the detection of adverse drug reactions that have occurred (Valderas et al., 2008). The transmission of reported symptoms from the patient to the clinician, from the clinician to the medical record, and from the medical record to the database through a research assistant is shortened by the use of PROM instruments and misinterpretations and omissions are avoided. By means of an electronic survey, the reported symptoms even flow directly into the database (Trotti et al., 2007). PROM instruments also enable the detection of profiles of side effects of known or new forms of therapy. With this information, the patient can be assisted in his treatment selection or it can be explained to him practically why a certain type of treatment was chosen. In this way, both the patient's perspective and the measurement of treatment specific benefits are included in the development process of primary endpoints of clinical trials (Patrick et al., 2007). Even though PROM's allow for the assessment of provider quality, the examination of procedures and strategies and help physicians to offer improved care, there are limitations to PROM's.

2.2.3 Limitations of PROM's

Some studies suggest that the potential of patient-centered outcomes is not fully realized and that the adoption of PROM's in the healthcare system is rare (Spertus, 2008; Wagle, 2017). This is probably due to the fact that clear evidence for the positive and direct impact of PROM's on the health status of patients is still missing (Valderas et al., 2008). The use of PROM's only had a positive impact on global quality of life and emotional well-being in one

study (Velikova et al., 2004). In other studies, however, neither effects on global quality of life nor on their individual dimensions were found (Drury et al., 2000; McLachlan et al., 2001). But besides procedural improvements, some of these studies also claim that PROM's are expected to have marginal or no effect on the actual health status of the patient (Espallargues et al., 2000; Greenhalgh et al., 2005). However, the cause for the differing effectiveness of PROM's is not clear (Greenhalgh et al., 2005). It is possible that the measures themselves are not fully effective or that the studies that have been conducted lacked theoretical and methodological correctness. Similarly, some limitations must be noted regarding the results of randomized controlled trials. Only a small percentage of the clinicians paid attention to the records that were made by the patients. On the other hand, the effectiveness of PROM's in the treatment of palliative patients may be different, or the data would need to be used differently than with a curative treatment approach (Drury et al., 2000). The fact that no difference can be found in terms of patient satisfaction may be due to a ceiling effect, as satisfaction can be already very high in the entire patient group (Detmar et al., 2002b; Taenzer et al., 2000). When offering specific interventions, only a third of all treatment options were seized by patients and somatic symptom management was accepted more frequently than psychological counselling. In addition, only a minor degree of disease-specific needs was reported by patients (McLachlan et al., 2001). In the following chapter, the most important findings from the literature regarding the implementation of PROM's will be discussed.

2.2.4 PROM Implementation

2.2.4.1 PROM methods and modes

The mode of PROM's can be either interviewer- or self-administered, whereas the method of the PROM is about the tool that is used to collect the data (Food & Administration, 2009). Most frequent tools are web-based data collection, paper-based surveys or electronic patient reported outcome (ePRO) devices such as interactive voice response (IVR) systems. PROM's are considered to be most valuable when they inform the provider precisely about the demands, preferences and priorities of the patient (Higginson & Carr, 2001). However, the measures that have been used in many studies mainly focus on prescribed health levels and do not fully reflect the patients' perspective (Carr & Higginson, 2001). Thus, it is expected that

the effectiveness of PROM’s in routine practice is ensured if they allow for a high degree of individualization (Greenhalgh et al., 2005; Kettis Lindblad et al., 2002). This way, valid information and increased pertinence for the patient are guaranteed. Likewise, a PROM can be considered useful only if it fulfils specific psychometric, developmental and scaling standards: The applied measures are supposed to be based on strong theoretical evidence and have to be in line with the respective target group (Gnanasakthy et al., 2013). Moreover, the measurements are expected to fulfil requirements in terms of validity and reliability in order to ensure true and comparable feedback. Before putting the PROM into use, it has to be examined if the structure of the scale should include only one or several domains and there has to be sufficient methodological justification for applying summary or scale ratings. As mentioned before, PROM’s should also measure the long-term impact of an intervention so that the quality of the intervention can be assessed further. Following this, the same standards should be used in different countries, but in order to ensure consistency and prevent from measurement errors the measures have to be adapted to different languages and cultures (Gnanasakthy et al., 2013). Likewise, patients might not be able to fully evaluate their health status or to communicate it properly (Eremenco et al., 2014).

2.2.4.2 PROM Implementation according to the ICHOM standard

For the Implementation of the standard sets ICHOM suggests a 4-step approach:

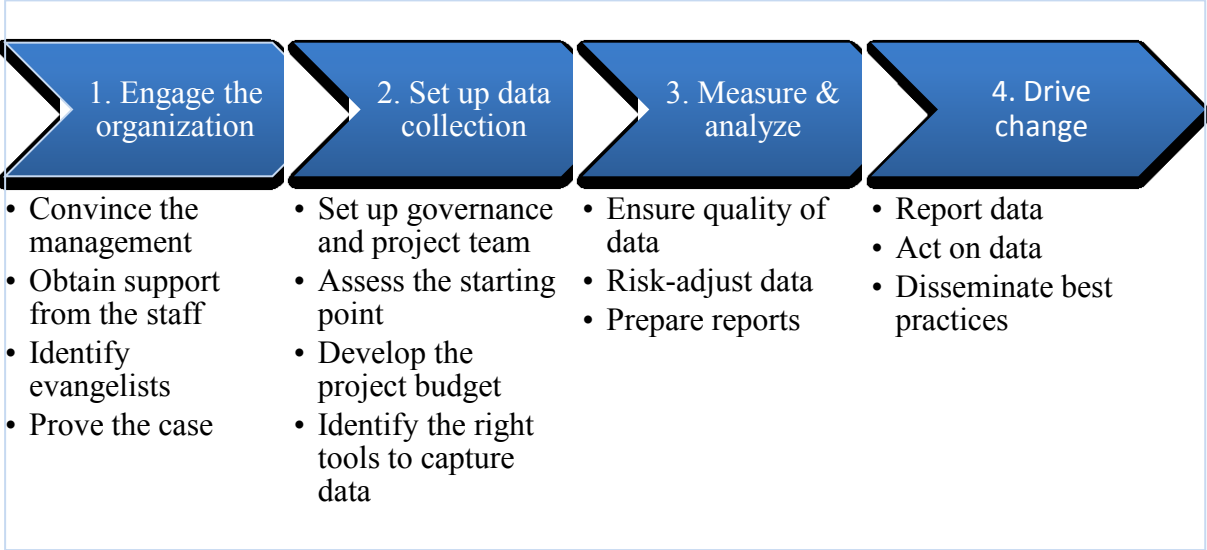


Figure 3: The “Implementation Journey” for ICHOM Standard Sets

Source: (ICHOM, 2017b)

The first step is about finding and engaging personnel that is motivated to implement outcome measurement (Arora et al., 2016). Likewise, it is necessary to convince the executives and other responsible individuals to install measurements. Ideally, the team consists of members from different disciplines, that first determines the present state of outcome measurement and then defines a target that they want to achieve. Arora et al. (2016) also suggest involving departments first that already conduct outcome measurement, since this is an indicator for commitment and competence in this field. Coming up with a detailed plan for the implementation ensures a structured approach and a higher chance of success. In the next step, the journey of a small designated patient group throughout the treatment has to be observed and potential opportunities for data collection have to be identified (for example when the patient enters the facility). Following this, the way in which the data will be collected has to be determined (for example a computer or paper-based survey). Data quality and exactness can be guaranteed if the data collection tool is regularly evaluated and checked for potential improvements. The third step is about checking if the desired data is actually measured accurately. Subsequently, the results should be presented in a way that allows to reach the previously set goals in the best way. Finally, conclusions from the data can be drawn so that best practices and possibilities to improve can be derived and implemented. Probably, the data collection process has to be changed from time to time, since small mistakes and drawbacks like measurement errors might emerge. As soon as the outcome measurement was successful with the small patient group, the measurement can be extrapolated to larger patient groups, different clinics and other hospitals (Arora et al., 2016).

Ackerman et al. (2018) mention that the implementation of the ICHOM standards for Hip and Knee Osteoarthritis in a private and in a public hospital in Australia was feasible. The implementation of the standard set (including data collection for 17 months) resulted in costs of about 100.000 Australian Dollars. Payments to the project coordinator were the highest cost component, followed by costs for IT support, ICHOM implementation support, equipment and consumables and a Pre-admission clinic physiotherapist.

Since evaluating of multidimensional surveys can be complex, Skevington et al. (2005) suggests that providers should receive respective training.

2.2.4.3 *Benefits ICHOM Standard Sets*

Interviews with patients and clinicians made clear that the patients did not always understand the reasons for data collection, but perceived them overall as valuable and minimally burdensome (Ackerman et al., 2018). Likewise, the personnel considered the standard sets as valuable and mentioned that they measure relevant aspects that have not been measured before.

2.2.4.4 *Disadvantages ICHOM Standard Sets*

However, it was also stated that the standard sets represent additional bureaucratic and administrative effort, which is likely to absorb manpower (Ackerman et al., 2018). Thus, the researchers recommended to narrow down the surveys to most relevant factors.

2.2.5 Impediments for PROM implementation

In general, practitioners perceive that the importance of PROM surveys in clinical practice is high, but only half of the examined practitioners actually survey the QoL, regardless of a curative or palliative treatment approach (Morris et al., 1997). The majority of clinicians often use existing PROM's only informally and inconsistently (Halyard & Froiland, 2008). In a study about the general knowledge of practitioners regarding QoL and PROM's, only a third of respondents were familiar with QoL survey methods, although 80% of respondents favor QoL assessment in clinical routine (Bossola et al., 2010). Insufficient information on available survey tools, their analysis and interpretation seems to discourage practitioners from using PROM's. In particular, physicians who had no experience with QoL data in clinical trials feared that their clinical decision-making could be complicated by PROMs (Barlési et al., 2006). Furthermore, many clinicians assume that they are able to fully assess the subjective feeling of a patient just as if the patient provided the information (Basch, 2010).

In view of this heterogeneous state of knowledge, it is not surprising that the use of PROM's has not been widely implemented. Greenhalgh et al. (2005) claims that the present randomized controlled trials have failed to provide the desired information, and that implicit assumptions associated with the evaluation of the use of PROM's were not ideally adhered to in these studies. Such assumptions are described as follows: 1. Existing desire of the patient to

talk to the attending physician about the patient's desire for his or her health-related quality of life. 2. Given self-image of the doctor to talk with his patients about QoL and therefore also to discuss the results of the PROM's. 3. Clinicians see QoL as clinically meaningful, which is why they will adjust treatment accordingly.

2.3 Quality of Life measures

2.3.1 Quality of life measures definition

One sub category of PROM's are QoL measures, which are defined as tools that measure the psychological, physical, functional and social health status of patients (Carr & Higginson, 2001). They help to assess the economic as well as the patient-specific advantages and disadvantages of a treatment properly.

The growing interest for the changes in the QoL of patients becomes visible when looking at the number of scientific publications about this topic in the last decades: In the b-on database, 8,848 scientific publications with the term “quality of life” in their title could be found between the years 1966 and 2000 (B-On.pt, 2018b). In the following 18 years, these numbers increased almost fifteen fold so that 128,764 publications can be found by applying the same search criteria (B-On.pt, 2018a).

One possible explanation for this is that research about outcome measurement and health-technology is expected to facilitate the evaluation of the net benefit, cost – and overall effectiveness of innovative medical treatments (Testa & Simonson, 1996). This way, it can be determined if the investment in a new form of treatment will actually pay off.

Moreover, QoL assessments can be used to evaluate the results of clinical trials and the performance applied disease management, to monitor routine clinical care of patients, and to improve quality by comparing outcomes with other doctors and clinics (Spertus, 2008). QoL measures also tend to be suitable to collect information about symptoms, which is why it is recommended to use them for example in clinical trials for lung cancer (Huschka et al., 2007; Paul et al., 1991).

2.3.2 Impact of QoL measures on clinical trials

In a literature review from Lemieux et al. (2011) it became clear that health related QoL (QoL) measures affected the decision making in clinical trials only in 30.1% of the analysed trials. In their previous study this percentage was only 15.2%. One possible reason for this might be that there was insufficient compliance and study design, false schedules,

implementation of invalid or too specific assessment tools that caused erroneous or inaccurate assessments. Another common issue with clinical trials in general is the low number patients within target groups so that results might not be representative for the whole population of similar patients (Bjordal, 2004). Similarly, inaccurate evaluations and demonstration may be further reasons for missing implementation of QoL into clinical practice. Assuming that the studies were meticulously designed and correct and stable measures were used, it is still possible that practitioners might be unfamiliar with the existing system of measurement. Thus, available data cannot be fully applied due to the missing ability to interpret results and identifying the clinical importance of certain scores.

2.3.3 Impact of QoL measures on Patient-provider communication

Apparently, many health care professionals would like to integrate QoL measures in their daily clinical practice (Jacobsen et al., 2002). One reasons for this might be that QoL measures can be applied in different ways: Enhancing the correspondence of patient and physician, standardize the exchange of information between provider and patient, check the success of a treatment regularly, identify starting diseases and report the holistic health status of the patient (McHorney & Tarlov, 1995). QoL are also considered to facilitate the identification of problems and needs of patients (Detmar & Aaronson, 1998; Detmar et al., 2001). Patients also tend to perceive that computerized surveys facilitate the communication about problems and needs (Velikova et al., 1999; Velikova et al., 2001; Wright et al., 2003). Likewise, physicians perceived the assessments as extension of the clinical interview, which improves the detection of changes over time and identifying topics that should be discussed. Similarly, if QoL information is collected from cancer patients, it is more probable that the physicians will talk about associated topics with the patient. It has also been shown that doctors and health care professionals are mostly not able to assess the mental state and overall QoL of cancer patients correctly (Slevin et al., 1988). Therefore, Slevin et al. (1988) suggested that this assessment is conducted by the patients themselves. Homsy et al. (2006) also found that open-ended questions revealed only 31% of severe symptoms and 21% of potentially harmful symptoms in comparison to a 48-question survey. Therefore, QoL measures are expected to increase the patient-provider communication significantly.

2.3.4 QoL implementation

When installing QoL measures certain points have to be taken into account: In general, the survey should be concise and it should be easy to understand so that patients can fill it out on their own (Bjordal, 2004). On the other hand, the tools should allow health care professionals to rate and evaluate given data easily. Practitioners are likely to face a trade-off between feasibility and validity. However, every aspect that is relevant for the target group should be included. If possible, minimal floor or ceiling effects are presented and the complete scope from disabilities to well-being is provided (Bjordal, 2004). It is also very important to be able to monitor the respective reaction of each patient towards changes in treatment. Proper clinical decision-making and screening require most accurate assessments, preferably with reliability levels above 90%. Scientific literature and expert knowledge form a basis to develop predetermined cut-off limits.

2.3.5 Requirements for QoL measures

In general, QoL measures have to fulfil five different requirements: First, the measure has to be valid, which implies that the measure really measures the QoL and not anything else (Garratt et al., 2002). Likewise, the tool should be appropriate for the selected target group and should be accepted by the patients. In terms of reliability, the physicians have to ensure that the measure will lead to identical outcomes when it is used repeatedly for the same target group. Moreover, the instrument should be able to notice changes in the answers so that the future treatment can be adapted if necessary. Finally, the outcomes of the measurements should be interpretable, meaning that the outcomes should provide relevant information that can be actually be interpreted by practitioners.

However, the application of these measures is rarely standardised within clinical trials so that the comparison of outcomes might be distorted. Some authors of previous literature reviews mentioned that there were many researchers who did not use suitable QoL measures but claimed that they evaluated the effects of certain treatments by measuring outcomes that were of importance for patients (Baker et al., 2000; Duncan et al., 2000; Fitzpatrick et al., 1998; Hayes et al., 2000; Stewart et al., 2001).

2.3.6 Limitations of QoL

Besides the many application areas for QoL, there are some limitations for the usage: QoL is subjective and patients that suffer from the same condition and receive the same treatment might evaluate their QoL very differently (Baron, 1987). The issue of subjective evaluation of patients regarding treatment performance is described by the disability paradox (Higginson & Carr, 2001). Patients that suffer from serious or even critical conditions may not rate their QoL as significantly lower as patients that are healthy or slightly ill. The reason for this could be that patients differ regarding the support they receive through friends and family or the experience of similar events. However, resource allocation becomes more complicated when groups of patients with different diseases cannot be compared accurately. Mount and Scott (1983) compare the assessment of the QoL through QoL measures with assessing the beauty of a rose through different measurements. One can measure the degree of redness of the leaves, their size, olfactory factors, but the complete beauty cannot be explained just by summing up these factors. Apparently, the same applies to QoL measures, since they are expected to not fully explain QoL.

QoL measures have been used as an outcome in the United Kingdom (UK) for clinical trials in rheumatology for over 20 years (Carr et al., 1996). Nevertheless, there are many studies that claim that these measures are rarely used in clinical practice. In a similar way, QoL measures are not expected to influence clinical decision making even when they are used in clinical practice (Kirwan et al., 1983). Thus, just raising the QoL and passing on the scores to caregivers was not enough to improve patient satisfaction and QoL. However, personalized patient-specific advice on how to adjust clinical care may have a positive impact on patient satisfaction and QoL (Rosenbloom et al., 2007).

The main reason for implementing QoL measures in clinical practice is to make sure that treatment plans and assessments are based on the patient and less on the disease (Higginson & Carr, 2001). However, besides QoL there are other ways to assess patient related outcomes for example through measures that deal specifically with mental health, social conditions or disability. Thus, QoL measures do not replace the measurement of disease related outcomes but can be seen as an extension to them: For instance, oncologists do not treat cancer with cancer fighting drugs just based on QoL outcomes. Likewise, if the intervention is intended to

accomplish a certain goal, measures for particular health outcomes like depression or anxiety are likely to be more useful, precise and responsive in comparison to general and diversified QoL measures (Higginson & Carr, 2001). Moreover, there is the possibility that staff might reduce their efforts to communicate with patients regarding their overall well-being since they assume that the QoL measures are sufficient to do this. Subsequently, the patients may experience a worse treatment in terms of involvement of health care professionals. On the other hand, there is an ethical issue coming from QoL measures: The result of the QoL assessment might overlap with the own assessment of the patient, so that the patient might feel worse after receiving an assessment that is inferior to the own one (Feinstein, 1992).

Reasons for clinicians to use PROM's only sporadically or why they do not capture QoL at all will be discussed in the following section.

2.3.7 Obstacles for QoL measures

There are many explanations why doctors are reluctant to the usage of QoL measures: the lack of time and resources, the lack of a suitable instrument, the assumption that the subjective assessment of the patients' QoL by the practitioner is sufficient (Luckett et al., 2009), that purely somatic aspects outweigh QoL (Morris et al., 1997), lack of comparability of PROM instruments (Barlési et al., 2006), and doubts about the methodology of life-quality assessment (Bossola et al., 2010). Snyder et al. (2010) identified additional arguments against the use of PROMs in an interview study: not all questions of a QoL questionnaire are relevant for each patient. In an established physician-patient relationship, PROM data could be considered obsolete and the PROM instruments placed an additional burden on the patient.

In a study by Detmar et al. (2002a) with palliative patients, treatment was adjusted in one-third of cases to improve QoL, but clinicians gave priority to overall QoL rather than specific areas. This may have been the case as the expertise in dealing with different QoL profiles was inadequate. In the case of tumor progression or treatment toxicity, consideration of the QoL became less important altogether. However, to ensure the benefit of PROM data for clinical routine, it must be specifically collected, evaluated and interpreted by specially trained personnel and finally included in the treatment. Higginson and Carr (2001) also claim that in order to ensure that QoL measurements have an impact on clinical practice they have to be a fixed component of the decision-making process for treatments. This aim can be achieved, if

QoL measures identify issues and preferences of treatment of the patient so that shared decision making regarding the goals of an intervention can be realized. And although PROMs have been used in clinical trials, there is rarely a clear structure for their actual use, interpretation, and following interventions (Luckett et al., 2009). Thus, the often random and indeterminate use of PROMs in clinical trials can be an obstacle for obtaining significant treatment outcomes through this data, which hampers the adaption of PROM's in clinical practice.

3 Methodology

At first, a list of journals and databases with a high reputation were consulted in order to identify highly relevant journals, which seemed safe to provide high quality research about impediments for outcome measurements. Subsequently, a search term was created which included the terms “VBHC”, “Outcome measurement”, “PROM”, “QoL”. These terms were combined with various synonyms for the terms “impediment”, “implementation” and “factor” to narrow down the search results. The papers examined have almost exclusively been published between 2000 and 2018 in order to receive a very current insight into the research of impediments for PROM’s and QoL. Ebsco was the main database for this thesis, because it is scientifically recognized, easy to handle and provided most of the relevant journals. Nonetheless, J-Store or GoogleScholar have been used when Ebsco did not provide certain journals or papers. At the beginning of the search process, a journal was selected which appeared to provide relevant findings with high probability. Consequently, the journal was examined for papers that contained similar terms to the search term in their title. The titles of the search results have been checked successively. When the title of a paper seemed to offer findings concerning impediments for outcome measurement, the abstract and if necessary further parts of the paper have been read in order to identify if there was a key finding about an impediment for outcome measurement. Whenever a key finding was present, the paper was downloaded. Name of the author, year of publishing, journal name, paper title, research method, key words and key findings of downloaded papers have been recorded in a table. The downloaded papers have been saved in files according to their key findings. More than 100 scientific papers were examined, but for this paper only topics which have been treated multiple times will be emphasized, as these topics seem to be highly relevant.

For the empirical part of the research, a deductive approach was chosen because it provides the most structured approach when considering the first part of the thesis. Each category was coded and examples were provided. for each research question, several hypotheses have been developed, which were based on the findings from the literature review.

A deductive content analysis according to Mayring (2000) is structured as follows:

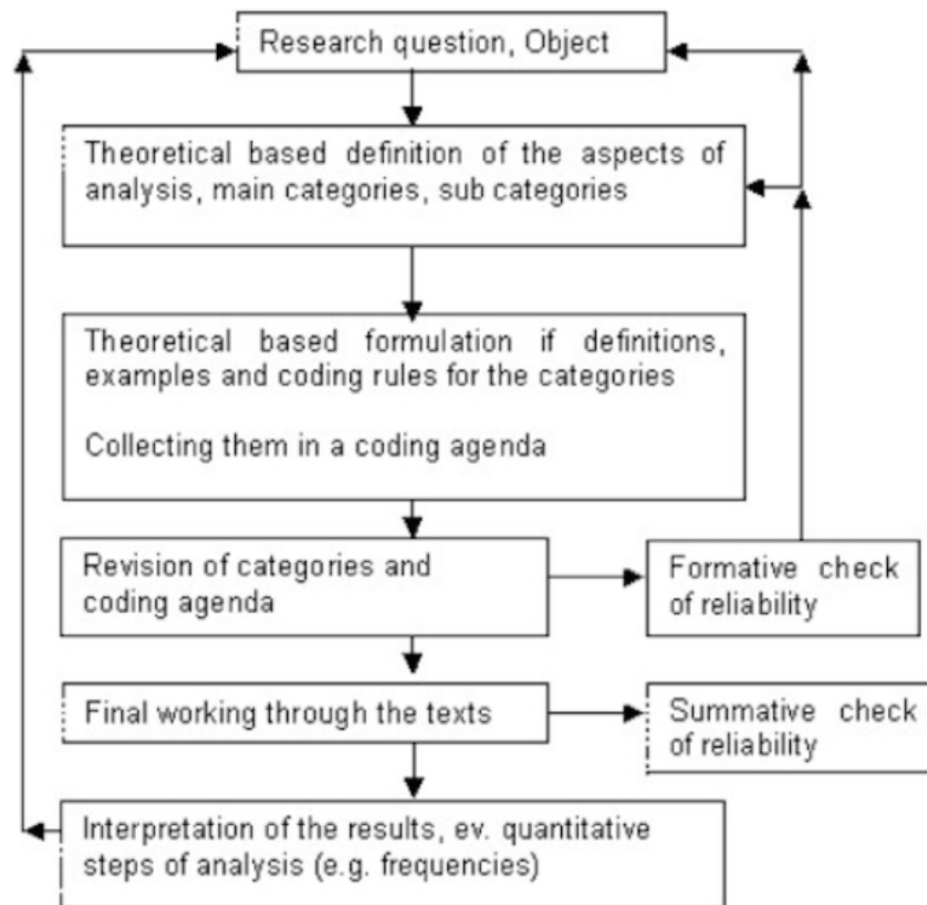


Figure 4: The qualitative deductive approach according to Mayring

Source: Mayring (2000)

The interview guideline was applied on all leaders in the study, although some questions were added or modified dependent on certain situations or on the individual. The interview partners were carefully selected to provide a broad overview of different leadership positions in private practices or university clinics and hospitals. In total, 5 medical professionals with leadership experience have been interviewed: Ms. Dr. Berghaus, Head of an ENT practice in Berlin, Germany; Mr. Prof. Dr. Berghaus, former director of the ENT department of the University Clinic of Grosshadern in Munich, Germany; Mr. Prof. Dr. Hellweg, Managing senior physician of the Department of Psychiatry and Psychotherapy of the Charité - University Berlin, Germany; Mr. Dr. Alexander Limburg, Head of a practice for gynaecology in Munich, Germany and Mr. Prof. Dr. Weiss, director of an orthopedically oriented magnetic resonance imaging (MRI) facility in the hospital Havelhöhe in Berlin, Germany. The respective interviews have been transcribed and translated from German into English and can be found

in the Appendices 1-5. The interview method was chosen in order to obtain in depth information about the perspective of the physicians and to ensure complete answers.

4 Results

4.1 RQ1: How familiar are medical professionals with QoL measures?

4.1.1 H1.1: MP's assess the success of their treatment primarily without PROM measures.

Basch (2010) and Luckett et al. (2009) mentioned that MP's sometimes refuse to use PROM measures in order to evaluate the success of a treatment, because they think that other approaches are superior. Mr. Prof. Dr. Berghaus (No.4) and Ms. Dr. Berghaus (No. 8,10,12) mentioned that they do not use feedback of patients primarily to assess the success of a treatment, but rather the clinical assessment. In contrast to this Mr. Prof. Dr. Weiss (No. 10) uses subjective criteria like well-being as well as several objective criteria like medical tests and imaging techniques (X-Ray, ultrasound, CT, MRT). Besides basic knowledge, experience, technical and social competence, Mr. Dr. Limburg mentioned explicitly that he uses feedback from patients to determine the success of his treatments (*Mr. Dr. Limburg, No. 8*). Mr. Prof. Dr. Hellweg (No. 4) compares an expected value of the condition of a patient with the actual observed value and draws conclusions from the difference he observes. His experience and scientific literature help him to classify certain severities of illnesses and he also uses questionnaires to determine the success of his treatments. This is due to the fact that in psychology classical scientific parameters cannot be used.

4.1.2 H1.2: MP's do not consider it important to assess the outcome of a treatment by asking the patient for feedback.

As mentioned before, Basch (2010) and Luckett et al. (2009) stated that the opinion of the patients about their own health status is rarely asked for by MP's when they assess the success of a treatment. Even though Mr. Prof. Dr. Berghaus does not include patient feedback primarily in his assessments, he thinks the feedback of patients is extremely important for determining the success of a treatment, *"because the patient is the one who is at issue, and the question of how he feels after treatment is simply indispensable"* (*Mr. Prof. Dr. Berghaus, No.6*). Likewise, Mr. Prof. Dr. Hellweg (No. 6) mentioned that, it is indispensable in the field of psychology to ask patients for feedback in order to determine the success of treatment. This

is “because it is very tricky in some patients that the subjective perception is different from the objective ones” (Mr. Prof. Dr. Hellweg, No. 6). Mr. Prof. Dr. Hellweg (No. 6) also thinks that personal feedback should be used more in somatic medical disciplines like oncology and hemato-oncology, because their perception regarding the success of the treatment is important as well. Mr. Prof. Dr. Weiss (No.12) and Mr. Dr. Limburg (No.10) confirm that the feedback of patient is essential in order to determine the success of a treatment. Mr. Dr. Limburg (No. 16) also mentions that patients usually reward a proper treatment with a life-long loyalty and that doctors who do not internalize their QoL cannot be considered to be good doctors.

4.1.3 H1.3: MP’s are not familiar with QoL measures

Similar to the findings from Bossola et al. (2010), most of the interviewed doctors would like to implement QoL measurements, but are not familiar with the respective methods. Ms. Dr. Berghaus (No. 18,30) has no experience with measuring QoL, but has heard about application of QoL measures for tumor patients. Mr. Prof. Dr. Weiss (No.16) has read about health-related QoL measures, but does not know them in detail. Mr. Dr. Limburg (No. 14) knows about health-related quality of measures and gave the example of on older patient who refused treatment for breast cancer, since she also deals with severe back pain and respective surgeries. In contrast, Mr. Prof. Dr. Berghaus, (No.10) conducted several QoL studies already in order to determine the long-time impact of certain surgeries like ear reconstruction. Mr. Prof. Dr. Hellweg (No. 8) is also very familiar with QoL measures, since he applies them during clinical studies as well.

4.1.4 H1.4: MP’s are not familiar with tools that allow the measurement of QoL

According to Bossola et al. (2010), MP’s also lack familiarity with tools that are necessary to measure QoL. In contrast to this, Mr. Prof. Dr. Hellweg (No. 10) knows several measuring instruments. Most of them are based on surveys and are adapted to the specific mental illness of the patient. Similarly, Mr. Prof. Dr. Berghaus (No.12,16) used several tools like the "Glasgow Inventory Scale" and the “Nose-Score”. Ms. Dr. Berghaus (No. 20) understands the application area of QoL measures, but did not mention a specific tool. Mr. Prof. Dr. Weiss (No. 22) is not familiar with any tools that allow the measurement of QoL.

4.1.5 H1.5: QoL is not measured in the department of the MP nor in their organization

Mount and Scott (1983), Baron (1987), Higginson and Carr (2001) mentioned that QoL studies are often not conducted, because QoL is too subjective and varies from person to person. Prof. Dr. Weiss (*No. 14, 24*) mentioned the exact the same reason for not to measuring QoL in his organization.

Ms. Dr. Berghaus (*No. 20,24,26,32*) and Mr. Dr. Limburg (*No. 22*) consider it to be sufficient to determine QoL on their own and on an oral basis at their practices, which was also described by Basch (2010) and Luckett et al. (2009). Thus, no QoL-questionnaires are used at their practices or at their organizations. Mr. Dr. Limburg (*No. 24,26*) says that communicating with the patient directly makes a questionnaire superfluous and adds that intuition and instinct are more important to gain the trust of a patient. A questionnaire might be insufficient in this regard. In contrast to this, Slevin et al. (1988) stated that doctors often fail to determine the mental state of their patients correctly just on an oral basis. However, Snyder et al. (2010) emphasize that QoL measures can display a burden or are obsolete for patients that already have a trustful relationship with their doctor.

Mr. Prof. Dr. Hellweg (*No. 12*) conducted several QoL measurements within clinical studies. Especially in the areas of dementia and gerontopsychiatry.

4.1.5.1 H1.5.3 MP's conduct paper-based QoL measurements instead of electronic QoL measurements

According to Pearson et al. (2016), electronic QoL measurements that are conducted on computers or mobile electronic devices like tablets have several advantages in comparison to paper-based QoL surveys: the patients data can be stored and evaluated immediately with respective statistical software. However, Mr. Prof. Dr. Berghaus (*No.18, 20*) used paper-based QoL surveys before and after treatment and in certain cases up to 7 years after the treatment to identify the long-term impact of interventions. In the case of Mr. Prof. Dr. Hellweg (*No. 18*), more paper-based surveys were used in the past but now they become more electronic. This is due to the fact that there are more multicentre studies which are standardized and checked for comparability by so called monitors. The organization of Mr. Prof. Dr. Hellweg tries to have a

paperless medical record of patients and is close to achieving these goals (*Mr. Prof. Dr. Hellweg, No. 20,22*). In his case intervals for the surveys depend on the respective study. *“There are studies where daily visits are scheduled, sometimes weekly, sometimes monthly.”* (*Mr. Prof. Dr. Hellweg, No. 22*). In order to identify the development of cognitive functions for dementia studies, surveys are conducted over half a year at minimum.

4.2 RQ 2: How do medical professionals categorize QoL measures?

4.2.1 H2.1: MP's do not know how to apply QoL measures correctly

Since, MP's tend to overestimate their understanding of QoL measurements, the interviewees were asked how they would conduct an QoL survey (Baker et al., 2000; Duncan et al., 2000; Fitzpatrick et al., 1998; Hayes et al., 2000; Stewart et al., 2001). Mr. Dr. Limburg (No. 36) emphasizes that QoL is highly subjective and wonders if there are tools that could allow for a conclusive measurement. For him, the official definition of QoL is insufficient, since it focuses only on the condition of the patient in context of a disease (*Mr. Dr. Limburg, No. 42*). He states that maintenance of health and medical provision and aftercare are equally important to QoL (*Mr. Dr. Limburg, No. 48, 50, 52, 54*). According to Mr. Dr. Limburg (No. 56), during the measurement of QoL it is important to validate if the answers of the patient are in line with reality in order to be able to really improve processes. It is also important to ensure that the survey really reflects the condition of the patient. Mr. Prof. Dr. Weiss (No. 32, 34, 36) heard that many researchers try but fail to determine factors that explain QoL. The main problems from his point of view are subjective and biased questions where the answer is already directed in one direction by posing the question in a certain way (*Mr. Prof. Dr. Weiss No. 34, 36*). Likewise, Gnanasakthy et al. (2013), mentioned the importance of validity and reliability and that the surveys have to be adapted to cultures and languages. Similarly, Mr. Prof. Dr. Weiss states that patients vary greatly in the perception of their health or disease, so that the measures have to be sorted “*by age, correct it by gender, correct it by geography, sort it by racial or nationality (...), by geographic and genetic positions and dispositions.*” (*Mr. Prof. Dr. Weiss, No. 56*).

Mr. Prof. Dr. Hellweg (No. 34) considers factors like gender, age, cultural background and level of education in particular, since they are very likely to influence the perception of patients regarding their QoL. There might be standardized surveys in English, but that does not guarantee that they are equally understood by people from different cultures. Mr. Prof. Dr. Berghaus (No.74) emphasizes that the questionnaires should be adapted to foreign languages, while making sure that the questions are understood in the same way. Thus, sociologists, semantics or linguists might have to be involved. One example from Mr. Prof. Dr. Berghaus (No.34) of the usage of QoL measures was for a study that examined the impact of setting back ears. The QoL development was positive and enforced Mr. Prof. Dr. Berghaus to

continue with this kind of surgery. Mr. Prof. Dr. Berghaus (*No.38, 42*) takes into account the facts that were mentioned by Bjordal (2004) and Garratt et al. (2002): He appreciates the usage of standardized and validated surveys and emphasizes that all patients have to be asked the same questions and that the surveys have to be completely and properly answered. This could be problematic if patients live further away, because then they might not know how to answer or do not answer at all. Thus, the surveys are conducted at the clinic ideally. For Mr. Prof. Dr. Hellweg (*No. 36,38*) it is also important to have a proper randomization in the sample and to avoid missing data, because if there are not enough answers it becomes problematic to make proper scientific assumptions. It is possible to extrapolate from given data, but this can falsify the results.

Ms. Dr. Berghaus (*No. 18, 36*) is familiar with QoL measures only from tumor patients and would like to use questionnaires to assess QoL. For these questionnaire, Ms. Dr. Berghaus (*No. 42*) would use closed “Yes-No” questions, since they can be evaluated the best and she would ask patients to show their pain or satisfaction on a scale of 1-10, since patients grasp this concept more easily. Homsy et al. (2006) suggested a similar procedure. Ms. Dr. Berghaus (*No. 66*) also suggests that the QoL measurements should be conducted by general practitioners, because they have the overview of the patient and can file all the treatments and effects that might take place in combination.

4.3 RQ 3: How do medical professionals evaluate QoL measures?

4.3.1 H3.1: MP's do not expect PROM's and QoL measures to be beneficial

As described earlier, MP's tend to neglect QoL measurements for different reasons (Barlési et al., 2006; Bossola et al., 2010; Lockett et al., 2009; Morris et al., 1997; Snyder et al., 2010). The interviewed MP's also seem to have differing opinions about the usefulness of QoL measures: Mr. Prof. Dr. Weiss (*No. 38,46,48*) cannot imagine how QoL measurements will be conducted from an organizational point of view. He expects that the patients are too diverse and that answers will be so diverse that it is not possible to develop universal statements for QoL. If patient-reported outcomes are included in daily practice, they have to be validated in order to ensure a proper diagnosis (*Mr. Prof. Dr. Weiss, No. 44*). Technically, patient surveys are prescribed within the quality management of private practices, but in reality, they are not conducted (*Mr. Dr. Limburg, No. 58*). According to Ms. Dr. Berghaus (*No.8*) asking for feedback is not beneficial in all cases and depends on the patient and the situation. However, judging the health-related QoL of patients is in general very important to Ms. Dr. Berghaus (*No. 22*). Like McHorney and Tarlov (1995), Ms. Dr. Berghaus (*No. 50*) considers QoL to be beneficial for the daily practice, since it allows for a more holistic view on the health status of the patient and decreases the risk of overlooking symptoms.

Mr. Prof. Dr. Berghaus (*No. 22*) sees PROM's and QoL measurements as beneficial, because they allowed him to assess the quality of his surgeries, which in turn improved his daily practice. However, he only conducted QoL measurements within clinical studies (*Mr. Prof. Dr. Berghaus, No.44*). To Mr. Prof. Dr. Hellweg (*No. 40, 42*), patient-reported outcomes and QoL measurements are very important, since he generally looks for the subjective and objective effects and side effects of a drug or treatment. Dowrick and Buchan (1995); Valderas et al. (2008) also stated that QoL measures are well suited for the detection of mental illnesses.

4.3.2 H3.2: MP's do not see a need within their organization to measure QoL

Since there are diverse potential reasons not to implement QoL measurements, the interviewees were asked about reasons that were relevant to them (Barlési et al., 2006; Bossola

et al., 2010; Lockett et al., 2009; Morris et al., 1997; Snyder et al., 2010). Mr. Prof. Dr. Weiss (No. 40, 52) does not see a need for QoL measurements in his organization, because of the difficulty of the instruments and mentions that there are already quality assurance standards in Germany. Those are standardized for physical and mental diseases. Moreover, they are highly regulated and evidence based. German doctors have to follow a very specific set of rules when treating a patient and there is hardly a possibility to improvise. This system exists for 15 years and is very successful.

Mr. Prof. Dr. Hellweg (No. 48) perceives the need that QoL measurements are conducted, but he also thinks that the existent tools are sufficient up to now. Before developing new tools he would suggest to adapt or modify the existing ones.

Mr. Dr. Limburg (No. 58) does not expect additional value by implementing QoL measures, because patients give him feedback indirectly by not visiting his practice anymore. This way he can see how satisfied patients are with his treatment. He can call his patients directly and ask them if something went wrong or why they do not show up anymore (Mr. Dr. Limburg, No. 60). Ms. Dr. Berghaus (No. 54) assumes that ENT doctors would like to have QoL measurements in 20-25% of the cases, whereas general practitioners could use it in up to 80% of their cases, because they need to have a holistic view on their patients. Ms. Dr. Berghaus (No. 58) also sees areas of application for neurologists, but less for orthopaedists, because they also have young patients who tend to have less QoL problems.

4.3.3 H3.3: MP's can imagine / have experienced advantages of QoL measurements

Ms. Dr. Berghaus (No. 62) mentioned similar advantages like Detmar and Aaronson (1998), Detmar et al. (2001), McHorney and Tarlov (1995): The doctor can easily adapt his treatment to the condition of the patient and that mental and social health aspects are also taken into account. Ms. Dr. Berghaus (No. 72) thinks that through QoL, processes would improve, because the interdisciplinary cooperation would be emphasized, which results in a more holistic medicine. She does not see any disadvantages for the health of patients through QoL measurements, *“because it's nothing invasive - It's a data query, so to speak, and that can only be for the benefit of the patient.”* (Ms. Dr. Berghaus, No. 82). Likewise, Ms. Dr. Berghaus (No. 74,78) assumes that the treatment would improve through QoL measurements, because superfluous treatments could be prevented and doctors would pay more attention to the mental condition of the patient and their usage of drugs. Similarly, Mr. Prof. Dr. Hellweg (No. 60) expects that the communication between the patient and the doctor improves through

QoL measures, because this could serve as a standard for all therapists so that all of them had to pay attention to the QoL of their patients. This is in line with the findings from Detmar et al. (2002b); Mathias et al. (1994); Skevington et al. (2005); Street Jr et al. (1994); Taenzer et al. (2000).

The results of the studies of Mr. Prof. Dr. Berghaus studies helped to improve the quality of surgeries, which is why for him the main advantage of QoL measures is to find out if the actions of the doctor actually contribute to the well-being of the patient (*Mr. Prof. Dr. Berghaus, No.50, 62, 72*). Doctors can also use QoL measurements to compare different kinds of treatment and to determine the better one (*Mr. Prof. Dr. Berghaus, No.64*). QoL measurements also helps to identify differences in the expectations of patients regarding the outcome of certain treatments (*Mr. Prof. Dr. Berghaus, No.66*). Some groups of patients might have higher expectations than others and therefore require a more profound introductory talk.

Similarly, for Mr. Prof. Dr. Hellweg (*No. 54, 58*) the big advantage of QoL measurements is the opportunity to compare different treatment options before and after the intervention. As a result, the doctor can optimize the treatment. On the other hand, Mr. Prof. Dr. Weiss mentions QoL measurements allow the patient to get information regarding a healthy lifestyle (*Mr. Prof. Dr. Weiss, No. 54*). The patient also becomes more autonomous in his decision making and can develop a better understanding of the treatment

Mr. Dr. Limburg (*No. 62*) mentions that he personally profits from the impersonal treatment of patients in clinics: “*Because they have a single contact person here who cares about them for decades, and in the clinic they are mass products.*” (*Mr. Dr. Limburg, No. 62*). Thus, QoL surveys would help especially big institutions to improve patient loyalty, understand patient migration and allow for significant improvement of their care as a result (*Mr. Dr. Limburg, No. 64*).

When asked about using QoL measures as a tool to compare performance between hospitals, Mr. Prof. Dr. Weiss (*No. 42*) answers that is not necessary in Germany, since comparisons already take place through rankings that are conducted by public newspapers. These rankings take into account how often a certain hospital conducts a certain operation and accordingly a high degree of quality can be expected. In addition to that, there are medical journals and magazines, which report doctors and hospitals who are very successful with the treatment of

certain diseases. This is contrary to the findings of Porter and Teisberg (2006) and Spertus (2008), who emphasize the advantages through comparisons of performance via QoL.

4.3.4 H3.4: MP's can imagine disadvantages of QoL measurements

Similar to Ackerman et al. (2018) and Lockett et al. (2009), Mr. Prof. Dr. Hellweg (*No. 16,20,30*), Mr. Prof. Dr. Berghaus (*No. 44, 52, 64*) and Ms. Dr. Berghaus (*No. 52,64*) mention that time constraints are the main reason for not implementing QoL measures on a regular basis: Bureaucracy and the required documentation for health insurances, authorities and legal protection make the realization unlikely. Mr. Prof. Dr. Hellweg also mentions that he “*would find it problematic if even more bureaucracy would come in at the expense of a direct individual doctor-patient conversation.*” (*Mr. Prof. Dr. Hellweg, No. 50*).

Mr. Prof. Dr. Weiss (*No. 58*) also indicates that the development of diseases like cancer is already sufficiently monitored by doctors. They apply standardized, evidence based and prescribed measures to observe the development and treat the disease accordingly. These optimal ways of treatments have been determined by studies, where it was validated that the suggested treatment is the most effective (*Mr. Prof. Dr. Weiss, No. 66*). Also in the case of Mr. Berghaus, the impacts of surgeries are already well studied and the additional value of continuous QoL measurement is questionable (*Mr. Prof. Dr. Berghaus, No.64*)

Mr. Prof. Dr. Weiss expects mainly organizational and financial problems when implementing QoL measures (*Mr. Prof. Dr. Weiss, No. 50,56*). He also wonders how QoL should be tested and how often. He claims that the possibilities to influence certain types of diseases like cancer are very limited and impossible to be predicted anyways (*Mr. Prof. Dr. Weiss, No. 60*). Therefore, a survey is not expected to improve the condition of patients with a disease such as terminal stage cancer.

The required long-term studies are also considered to be very expensive and difficult to realize, because patients have to answer these regularly over a long time (*Mr. Prof. Dr. Hellweg, No. 22*). In terms of processes there is an additional effort for the doctor and the employees through the implementation of QoL measures (*Mr. Prof. Dr. Berghaus, No.72*).

Especially in a private practice likelihood for implementation seems to decrease, because there is not as much personnel and the time for patients is strictly limited (*Mr. Prof. Dr. Berghaus, No. 50*). However, Mr. Dr. Limburg does not think that there are any disadvantages

for doctors that implement QoL measures, because it is likely to eventually improve quality, processes and time management. (*Mr. Dr. Limburg, No. 66,70*)

4.3.5 H3.5: MP's know / experienced impediments for QoL implementation

With regard to the findings of Ackerman et al. (2018) and Lockett et al. (2009), the interviewees mentioned further impediments for the actual implementation of QoL: One big impediment for QoL measurements seems to be finding agreement with patients that they are study patients, because “*sometimes they are hard to reach afterwards, because they moved or something similar (Mr. Prof. Dr. Berghaus, No. 74)*. On the other hand, patients maybe do not want to answer this kind of question or think that it is unnecessary (*Ms. Dr. Berghaus, No. 52,64*); *Mr. Prof. Dr. Berghaus, No.44*). Likewise, Mr. Dr. Limburg (*No. 72*) states that one of the main obstacles might be to convince patients about the necessity of the surveys: They have to be told that reason is to improve quality – maybe even for themselves. Just like Eremenco et al. (2014), Mr. Prof. Dr. Weiss (*No. 70*) adds that patients are often not able to fill out surveys, because they cannot classify their own situation properly. If an interview would be conducted, there had to be control questions that ensure that the patient had all his mental capabilities at disposal.

Mr. Prof. Dr. Hellweg (*No. 30*) also claims that patients expect individual interviews instead of just answering a survey. At his organization, the implementation of QoL measures on a daily basis is being discussed, but since practitioners have 15 minutes per patient a realization is not likely (*Mr. Prof. Dr. Hellweg, No. 30*). Similar to this, he explains that the organizational conditions at his hospital do not allow for a permanent assessment of QoL, since the focus is on efficiency: Patients are expected to be treated as quickly as possible in order to have enough available beds for potential new patients.

Mr. Prof. Dr. Hellweg (*No. 62*) sees two potential groups that can impede the implementation of QoL measurements: On one hand, the commission in hospitals which either supports research or not. On the other hand, he sees a big issue with privacy: Electronic and patient-related data has to be stored in a safe way and patients have to explicitly agree with that.

Ms. Dr. Berghaus (*No. 68, 94*) is convinced that the implementation of QoL measurements at her facility could be realised if the doctors would actually demand their usage. Moreover, she thinks that if the service remains unpaid, it is very unlikely that it will be performed.

4.4 RQ 4: Are medical professionals interested in gaining skills regarding QoL measurement?

4.4.1 H4.1: MP's do not know about specific skills and resources that are required for QoL implementation

Since, Bossola et al. (2010) and (Lockett et al., 2009) claim that MP's tend to have a lack of necessary skills to conduct QoL measures, interviewees were asked what they know about these necessary skills. Ms. Dr. Berghaus (*No. 86*) assumes the technical implementation of QoL measurements to be really easy: She assumes that it mainly requires a valid and standardized questionnaire, a printer and software tool that evaluates the results. Nevertheless, the doctor should still talk to the patient and discuss the results.

On the other hand, Mr. Prof. Dr. Berghaus (*No. 76.*) emphasises the importance of statistical and organizational skills and understanding the tools at hand. According to Mr. Prof. Dr. Weiss (*No. 74*), large amounts of data have to be collected digitally. This is also because statistical analyses are applied. QoL measurements also require a lot of additional work, which in turn requires manpower and salaries for these employees. (*Mr. Prof. Dr. Berghaus, No.60*). In order to carry out QoL measurements, competent personnel is essential as well (*Mr. Dr. Limburg, No. 78*). There is the opportunity to apply for third party funds, but nowadays the justification must be really good in order to receive these funds (*Mr. Prof. Dr. Berghaus, No.60*). Mr. Prof. Dr. Hellweg (*No. 66*) and Ms. Dr. Berghaus (*No. 68*) could imagine that support from health insurance companies could accelerate the implementation of QoL measurements. However, it must be proven that the advantages of the implementation really outweigh the disadvantages.

Moreover, it is important to analyse the data in a way that reveals potential for improvement and one has to be able to actually conduct the necessary improvements (*Mr. Dr. Limburg, No. 78, 80*). Patients will be frustrated if their participation has no effect and as a result might stop to contribute to surveys.

4.4.2 H4.3: The MP's do not perceive a need to acquire skills that enable QoL measurements within their organization

MP's were also asked if they plan to acquire the skills that are necessary to conduct QoL measurements properly, because Bossola et al. (2010) and Lockett et al. (2009) mentioned that a significant proportion of MP's have a lack of the required skills. Mr. Prof. Dr. Berghaus (*No.78*) mentions that it is not necessary for the doctor to have all the required statistical knowledge. Instead, it is possible to contact biometrical institutes, which are highly specialised in this area and can give comprehensive advice regarding planning, implementation and evaluation of results. Mr. Dr. Limburg states that he does not really require QoL measures, because patients will communicate dissatisfaction by not visiting him anymore (*Mr. Dr. Limburg, No. 88*). Nevertheless, he would not resist such measures, since they allow for quality improvements. He also argues that it would make sense even in small practices, since QoL measures allow to monitor quality (*Mr. Dr. Limburg, No. 84, 86, 88*). However, he points out again that practices are already supposed to do that, but in reality this is not conducted. Mr. Dr. Limburg does not perceive the acquisition of knowledge about QoL measurements as a significant organizational obstacle and suggests that patients could fill out the survey in the 10-20 minutes of their waiting time (*Mr. Dr. Limburg, No. 90*). Ms. Dr. Berghaus (*No. 96*) does not suppose that she would have to acquire certain skills in order to be able to implement QoL measures at her organization. Due to age related reasons Mr. Prof. Dr. Weiss (*No. 76*) has no incentive to acquire skills in the area of data collection.

4.4.3 H4.5: MP's can imagine that employees need to develop specific skills in order to allow for correct implementation of QoL measures

With accordance to Skevington et al. (2005), Mr. Prof. Dr. Hellweg (*No. 68*) thinks it is absolutely necessary to train the personnel to be able to implement and use QoL instruments correctly, because psychological surveys and their evaluation can be very complex. The employees of Mr. Prof. Dr. Berghaus also received training in statistics and similar subjects in order to be able to evaluate the studies correctly (*Mr. Prof. Dr. Berghaus, No.80*). Employees of Mr. Prof. Dr. Weiss are trained in the area of data management, but not in the field of QoL measurements (*Mr. Prof. Dr. Weiss, No. 78*). Mr. Dr. Limburg could imagine training his employees in the field of QoL measurement, because it would boost operations and quality management. (*Mr. Dr. Limburg, No. 94*). Ms. Dr. Berghaus (*No. 94*) expects that her employees do not have to be trained since it is not planned to introduce QoL measure.

5 Conclusion

In summary, it can be stated that all of the impediments for the implementation of QoL measures that have been mentioned by the interviewed doctors, have already been mentioned in the scientific literature. Similarly, almost all of the hypotheses which were based on the scientific literature have been confirmed. Regarding research question (RQ) 1, it can be stated that the interviewed doctors who already conducted QoL measurements were obviously experienced and familiar with their application. However, the other doctors had a rough theoretical understanding of QoL measures, but no in-depth knowledge. This is similar with the second research questions, which dealt with the categorization of QoL measures: MP's that conducted QoL measurements before, knew about most relevant statistical and organizational factors that had to be taken into account and could provide examples for their successful application. However, regarding the third research question the answers given by all the MP's were almost identical: It became very clear that time-constraints and bureaucracy seem to be the most relevant impediments for a permanent implementation of QoL measures in Germany: Doctors already have to provide a lot of documentation for health and legal institutions and the time that they can spend with each patient is strongly limited. Thus, doctors are not expected to appreciate an additional administrative obligation. Moreover, the mental condition of patients might be secondary in medical fields like surgery where the primary goal is to achieve a physical improvement.

Likewise, patients might not be able to determine their own health status correctly, which would result in falsified answers. This said, there are studies that show that QoL measurements are significantly better in determining the mental condition of patients in comparison to a usual physician-patient consultation. On the other hand, QoL measurements might represent a burden or are obsolete for patients that already have a trustful relationship with their doctor.

Other impediments for an implementation of QoL measurements that were stated by the interviewed doctors were doubts regarding organizational procedures: Such permanent surveys are expected to be costly and require the constant cooperation of patients. In addition, some patients might question the need for these kinds of measurements and might be reluctant to provide personal information due to data privacy reasons.

According to the examined scientific literature, reasons for the lack of implementation of PROM's and QoL measures mainly are: Low experience and/or undifferentiated experience

with the QoL concept, insufficient knowledge about available and validated instruments including their application, evaluation and interpretation (for both paper- and computer based versions), fear that PRO's will add complexity to the decision making process, impression that PRO's tend to require more resources than they save, assumption that ratings of clinicians are as valid as the self-assessment of patients as well as sparse and heterogeneous scientific findings regarding the usefulness of PRO's.

The willingness of the doctors to achieve skills that allow the implementation and conduction of QoL measures was rather low. Mainly because most of the doctors were close to retirement or because assessing the QoL of their patients on a verbal basis was sufficient from their point view.

Having in mind the prevailing lack of time and the fact that most doctors do acknowledge advantages of QoL measures like the opportunity to compare treatments and to enable a more holistic medicine, future research should focus on possibilities to introduce QoL measures in a way that is time-efficient and is easy to implement. Nevertheless, extensive evaluation studies are needed to remove any ambiguity about the actual impact of PRO and QoL surveys on the medical and psychosocial health status of patients.

5.1 Limitations

Limitations of this thesis include the fact that all of the interviewed doctors are close to retirement, so that they do not have an incentive to learn more about outcome measurement. It is also possible that the interviewed doctors and doctors in general gave socially desirable answers to questions regarding the implementation of QoL measurement, whereas they actually have a different opinion. Another limitation is that all of the interviewed doctors work either in Berlin or Munich, Germany. Thus, their answers can only be applied to a) Germany and b) cities with more than 1.5 million inhabitants. Answers might have been different from doctors from the countryside.

5.2 Managerial implications

If the management of a hospital considers the implementation of QoL, it should be aware of the fact that these measures are expected to be time consuming due to the additional administrative efforts. Having in mind that expenses for medical staff represent the most important cost factor in hospitals and private practices, the work of these employees should

contribute to the success of the organization in the most efficient and effective way. Therefore, the management should make sure that the additional effort through QoL measurements eventually pays off and results in treatments with an improved quality. In order to achieve this goal, practitioners and caregivers should be equipped with practical and reliable PRO tools and should be familiarized with the handling of electronic survey systems. Strengthening their understanding of PRO data and training of medical staff regarding the interpretation and incorporation of PRO data into the course of treatment is also expected to increase the likelihood of a successful implementation of QoL measures.

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6 Appendices

6.1 Interview with Ms. Dr. Andrea Berghaus

#	Interview
1	Hello Ms. Berghaus, Thank you for making yourself available as an interview partner! Is it okay for you If I record this conversation?
2	MS. DR. BERGHAUS: Yes, no problem.
3	VIKTOR: What is your name, career, occupation and current position?
4	MS. DR. BERGHAUS: Andrea Berghaus, quite a classic high school diploma, medical studies and now doctor or (female) doctor. I work in an MVZ (Medical Care Center) for the AOK (Allgemeine Ortskrankenkasse). The position I hold is called "Praxisleitung" (Practice management) ENT.
5	VIKTOR: Ok then I'll just start the first substantive question: To what extent do you think it is necessary to ask patients directly for feedback in order to assess the success of the treatment
6	MS. DR. BERGHAUS: That's very special, it depends on the patient and the situation on it. So do I have to specify that exactly?
7	VIKTOR: No, you can just freely express your thoughts.
8	MS. DR. BERGHAUS: No, that's very individual. So there is no stringent manual.
9	VIKTOR: Ok, so if you want to see the success of a treatment, can you do it without the patient's feedback?
10	MS. DR. BERGHAUS: That's right, yes. So by the local findings alone and you do not want the patient in part, you do not want to urge him to fall into praise.
11	VIKTOR: Ok, so what do you think? The majority of your treatments or the successes or even failures you can determine without the patient's voice.
12	MS. DR. BERGHAUS: In percent?
13	VIKTOR: Simply yes, whether it's more or less than 50%.
14	MS. DR. BERGHAUS: Yes, the majority.
15	VIKTOR: Ok, more than 50%. The following questions are about the health-related quality of life of patients. Is this term known to you?
16	MS. DR. BERGHAUS: Yes, so I know what that means.
17	VIKTOR: And what do you imagine?
18	MS. DR. BERGHAUS: One knows that from tumor patients right?
19	VIKTOR: Yeah, so what do you think of that?
20	MS. DR. BERGHAUS: Well, I think of seriously ill people, where it is no longer possible or possible to bring about healing. These are then measures that make it easier for people with the given situation, pain free and reasonably well to make ends meet. Like this.
21	VIKTOR: Ok that's definitely going in the right direction. I've picked out the official definition here and I'll just read it to you. Statement: In health care, health-related quality of life is a patient's assessment of how individual wellbeing over time is affected by illness, disability, or disorder. Health-related quality of life covers the status of psychological, physical, functional and social health. What would you say, how important it is to judge the health-related quality of life of patients?
22	MS. DR. BERGHAUS: Very important
23	VIKTOR: Ok, and does that happen to you in practice?
24	MS. DR. BERGHAUS: Yes, so I'm trying hard to do it that way!
25	VIKTOR: Ok, do you know measurements of health-related quality of life?

26	MS. DR. BERGHAUS: Well, we have no questionnaires about where you ask me now, I have to say: Unfortunately!
27	VIKTOR: So that's just going to happen on an oral basis.
28	MS. DR. BERGHAUS: Right, but this is not queried in a structured way.
29	VIKTOR: Ok, do you know a bit about measuring LQ?
30	MS. DR. BERGHAUS: Well, I myself have no experience evaluating such things. With me that is totally subjective.
31	VIKTOR: Ok with you at MVZ you know if there are areas where something like this is done?
32	MS. DR. BERGHAUS: No, so far as I am informed, this is not done at our facility.
33	VIKTOR: Ok, then we come to the last question in this block of questions: Are there perhaps efforts within the MVZ to use health-related LQ measures in the future?
34	MS. DR. BERGHAUS: So far, that's not an issue for us.
	VIKTOR: Ok, all right. Let's get to the next group of questions, so to speak. It's a bit about your understanding of LQ measurements.
35	So, if you could do it, how would you do health-related LQ measurements?
36	MS. DR. BERGHAUS: Yes, so I think a questionnaire is not bad. The same is built up, as you have just said: Psychological, social and so on. Where you have to put together few empirical questions that you then equip with a score. So what do you evaluate how, to come to a total score, which then for each chapter, so each of the four pillars and then you would get out limits and could find out where to look, where to rectify for the patient.
37	VIKTOR: Mhm, yes, ok, and you already mentioned an example for using such a measurement, can you perhaps go into that again? That's when you talked about tumors
38	MS. DR. BERGHAUS: Well, that's sort of the most dramatic chapter, so to say, of all illnesses, the most incisive for patients um, and of course this psychological and social aspect is very important. That the patients are caught, both in the family and in the social context and that they get things in the hand as the psychic covers everything and the pain therapy that would be the points that are important for these people.
39	VIKTOR: Ok, yes, then comes the next question and I would be interested in whether you or what your opinion is what factors in the measurement of health-related quality of life must be considered, so what to look out for such a measurement:
40	MS. DR. BERGHAUS: So now the subdivision of the question or what? So the weighting is already clear, so there you have already named these four pillars and within which I should now explain something again?
41	VIKTOR: Just in general, if you make such a measurement, so I say a scientific measurement, there are always so a few things that you have to consider.
42	MS. DR. BERGHAUS: So, yes, that there are general questions and that it, yes in the case I have to say, in the case are the best evaluated closed questions so Yes-No, with open questions brings more information, but are worse to evaluate. And what I like, if you do it in a scale, please excuse me if I say so, but as with hotels, where you say a big smile, I'm totally satisfied and painless, I'm all well and good. Other sign, where the corners of the mouth go down, I'm totally bad. And maybe even with notes and a scale of 1 - 10 or so.
43	VIKTOR: Okay, ok that the patient understands that anyway. Okay and..
44	MS. DR. BERGHAUS: Exactly, which I would find the best with the smileys in the case. I must say honestly.
	VIKTOR: Okay, let's get to the second to last question group. And that is exactly what we have already mentioned.
45	VIKTOR: So you think the measurements of health-related quality of life are useful in your daily practice? Did I understand correctly?
46	MS. DR. BERGHAUS: For useful?
47	VIKTOR: Yes, for useful yes.
48	MS. DR. BERGHAUS: Absolutely, absolutely yes. I can also give you an example after that.
49	VIKTOR: Ok, you're welcome now. Give your example.

50	MS. DR. BERGHAUS: Well, well, I had one or I have a very active patient, who is very active in his job. He was a shipbuilder and he came around the world and then came to me for a little something and we started the conversation and said "Yes it also hurts my hip, and I also have problems with the eyes and I also have double images ". And there was more and more and then I started to send him to the different disciplines and that ended up with the fact that he was also hospitalized because of these double images and then came a list of incredible illnesses, expired strokes and very marked and bad things also. And then he was there with these diagnoses and then came to me because of these ears, which had then but already improved. And then I asked him "What has become of this? There are 10 or 12 diagnoses. How are you now?" And there he says "Miserable!" and "I just sit at home, do not want to go out and I'm always sad and can barely go on the doorstep." And then, according to these diagnoses, there really came a wave of things that indicated his subjective state of health. So that was overwhelming and I thought I have to do something, although I was not responsible for this disease, but then suddenly this overall picture of diagnoses how bad he is. And then I turned to the family doctor and made all this, because I thought ok that must be managed in a central location. It does no help this man if he only knows all his diagnoses. It's also about that he is doing better and um that we have gotten so on the line, but if you had such a tool, you might have come faster behind it, what's going on with the man and how bad he is.
51	VIKTOR: Ok, and apparently you see an added value in these measurements. What do you think are or are the main reasons that these health-related QoL measurements are not being made at your facility?
52	MS. DR. BERGHAUS: Mhm, so generally not only for me, factor: time and the factor that I believe one is - how to say - is professionally blinkered.
53	VIKTOR: Ah yes, and what I also wondered, in what percentage of the cases you have, would you say, "I'd like to have a measurement now," or "I'd like to have a tool like that now that allows me to look at this".
54	MS. DR. BERGHAUS: Yes, the ENT is bad in this regard because the family doctors are the important contact persons. For me that's maybe 20-25%, but in a GP practice, I would almost say at least 80%.
55	VIKTOR: Ok, (80%) that could use something like this?
56	MS. DR. BERGHAUS: Exactly because that's when several diagnoses come together like the most common coupling diabetes and hypertension, so blood sugar and high blood pressure. And as soon as there is more, it is really important to know, how is it? Does he feel well with the medication or does he have various pains, even though he has been taking these tablets for 6 years?
57	VIKTOR: So you see, so to speak, with the family doctors, the great added value?
58	MS. DR. BERGHAUS: Yes, definitely with the neurologists, the orthopaedists are more difficult. It depends on the clientele. Since it is difficult, if the trauma surgeons only have young, lively people, that is different, when the average age is over 60. So I think the first two I've told you would have the most benefit. I think.
	VIKTOR: Ok
59	VIKTOR: Ok then I would be interested, where are the biggest advantages for you in such an implementation, so if you really implement that?
60	MS. DR. BERGHAUS: Advantages now only for the patient or for the doctor?
61	VIKTOR: Both as well.
62	MS. DR. BERGHAUS: So of course the doctor can respond much better to either too little medication, too much medication or wrong medication. Respectively social, psychological aspects, so that you don't focus excessively only on the pure illness from the disease, but perhaps also notes aha there is also a mental health problem that comes on top on this disease. So keyword chronic pain syndrome: The patients have also changes in their character then in the end so to speak. And the patient, of course, the same, of course, a mirror image – these character changes may derive from too much intake from false drugs. Considering that the patient lives in a social context and lighting what effects that has had on his soul - the disease.

63	VIKTOR: Ok and what do you think are the disadvantages of these measurements? You mentioned it roughly before.
64	MS. DR. BERGHAUS: So it's a time factor that has to be evaluated and it has to be reacted. And with the pre-existing five-minute medicine that's quite difficult. There are certainly patients who do not want this. Well, there you can say no, so to speak. And you mean as negative points. Factor time, evaluating, responding that all costs time, too. And the patient, that he does not feel like answering that. That he thinks that is superfluous, things like that. Violation of your personal rights or something, but I think that is very rarely the case. Patients are always happy when dealing with the environment of their illness. Not only say "Ah, he has a headache" or "He has a thyroid disorder", but they like it when they are perceived as a whole.
65	VIKTOR: And I would also be interested in: Are there any organizational obstacles that may play a role? So I wonder, you're really seeing an added value in these measurements. What do you think how easy it would be to start such an initiative and implement it?
66	MS. DR. BERGHAUS: So it should first be a standardized questionnaire. Which you can also provide with each other. So not everyone starts at A and B, you know? So it's stupid, if the patient is now held by each of these questionnaire and then he has no more compliance. This would have to be a standardized questionnaire, which later compares also ideally allows - The family doctors will cheer, because they have so much to do anyway - but that would ideally be in the hands of family doctors. That gets an overview of all treatments. It used to be thought that the family doctor should always be the point of contact and that the specialists work with him if necessary. This model is more and more torpedoed, because the patients can run everywhere, if they have something on the eyes or on the feet, they can choose the specialists and I think this is bad for the patient. In the past, there was a rule that the patient received a health certificate for the family doctor in the quarter and the family doctor delegated it when there were problems. As a result, he was always informed about what is going on with the patient. Unfortunately, this is not the case today. With the questionnaire, it would be just like that again, that in quotation marks again there would be a central office where it is done. Or you can say yes: Ok now the specialist just stops something on what has not been noticed, but then he has the standardized questionnaire also at hand and then provides him but the family doctor available. So finished, that would be a good idea too. So if this results in consequences, so if the says "Everything's great, everything great!" Then you do not need to throw this mill.
67	VIKTOR: Ok, and if such a questionnaire were to be implemented now, what do you think from where would the initiative come from? Does this have to go out of the company's management, so to speak, or does this have to come from the doctors, that something like that is implemented, right?
68	MS. DR. BERGHAUS: Yes, well, I think the doctors have to endorse the content and find it good and necessary. Then the health insurance companies have to play along, because that costs time. That means that would have to be compensated accordingly. So who fills out such a questionnaire blablabla and that does not remain unpaid is also important, otherwise no one does. And yes, I think that would be the right set screws.
69	VIKTOR: Okay, then my last question about this topic block or my last questions: what do you think these measurements would mean to the processes within your organization? Can you imagine anything there?
70	MS. DR. BERGHAUS: Yes, I think that would result in better interdisciplinary cooperation.
71	VIKTOR: Ok, just because the exchange is taking place between..
72	MS. DR. BERGHAUS: Exactly because of what now I think is so great at these oncology centers, is that not only a field of study deals with the patient, but all together you know at these tumor conferences and so on. So that would lead to a holistic medicine more. Not only now, but that would support that.
73	VIKTOR: Ok, and what do you think about how the treatment would change?
74	MS. DR. BERGHAUS: Yes, that would also be optimized. So double treatments would be

	eliminated, interactions would be more respected. A lot of chemical might also be eliminated by physical measures and yes also psychotherapeutic support and so on.
75	VIKTOR: And what do you think would change the communication between the patient and the doctor?
76	MS. DR. BERGHAUS: Improve.
77	VIKTOR: Just because of...?
78	MS. DR. BERGHAUS: Yes, because he is perceived as a whole. Because he is sometimes asked how he is, so more intense, more detailed. So because, one finds out where the shoe pinches, so to speak. And then he is also more forced to spend more time with the patient.
79	VIKTOR: And accordingly. Yes, exactly, then the final question would be here. So how do you assess the impact of these measurements on the health of the patients, how you would rate that.
80	MS. DR. BERGHAUS: So that can only be positive.
81	VIKTOR: So in any case, you would expect that to be a positive influence.
82	MS. DR. BERGHAUS: Yes, because it's nothing invasive. It's a data query, so to speak, and that can only be for the benefit of the patient now.
	VIKTOR: Yeah, well, I'll have one, then we'll come to the last block of questions. It's a bit about the future of this topic. Or in general, a few higher-level questions.
83	VIKTOR: Namely: What do you think are necessary skills or resources that are necessary to successfully implement LQ measurement measures?
84	MS. DR. BERGHAUS: What do you mean now? How to finance this? Or?
85	VIKTOR: So everything that comes to your mind. Everything that is for you the most important skills and resources.
86	MS. DR. BERGHAUS: Well, I, how can I say it's not difficult at all, in my opinion. What you need is a reasonable questionnaire, which is not difficult to create, if you're there - it's generally valid, so how should I say, where not every practice designs its own questionnaire. But if you - what's that called, if that's the case? Such a standardized, standardized questionnaire, which is available to all practices. Then you only need a printer to duplicate it. Then maybe you need an evaluation program - so that's all then PC then. So then you need an evaluation program and then you need a final / evaluation talk with the patient. So I would not be without, so I would not enter this score in the file and say "ok, that's it" without talking to the patient, so that's not possible. He has to be asked, but then he has to talk to the patient. So that's not complicated.
87	VIKTOR: But you've already said that it's not planned to do anything within your organization right now, and that none of these actions are planned.
88	MS. DR. BERGHAUS: No, that's not the case at all with us. Nobody talks about it.
89	VIKTOR: Ok and are you planning to take specific measures to establish or expand LQ measurements?
90	MS. DR. BERGHAUS: No
91	VIKTOR: Accordingly, it is out of the question that employees are trained in the field or?
92	MS. DR. BERGHAUS: No, that would have to be, let's say "born again".
93	VIKTOR: Ok, exactly, and when this is reborn, I actually already kind of asked that, that would have to be done by doctors, but also from the management floor, I say?
94	MS. DR. BERGHAUS: Well, well in the MVZ, well, if the doctors would now say, "Well, we need that and it has to be." And the data protection law goes, then they (the management) have actually little to turn against.
95	VIKTOR: Ok, so you would like to say so, or do you think that you still need to acquire skills in order to establish such a thing?
96	MS. DR. BERGHAUS: I do not think so.
97	VIKTOR: Well, alright I think were done now. Then we are so far through. At this point I thank you for your time and your support!
98	MS:BERGHAUS: No problem, you're welcome!

6.2 Interview with Mr. Prof. Dr. Alexander Berghaus

#	Interview
1	VIKTOR: Ok, so I pressed the recording. Well at the beginning a few questions that are superfluous, because your name, for example, I know yes. So, if you want you can probably just say something about your career, right up to your current position. So just a rough outline maybe.
2	MR. PROF. DR. BERGHAUS: I can say that I am a doctor of the otorhinolaryngology and have studied medicine in Homburg on the Saar, in Bonn and in Berlin. Since then in Berlin, I have also made state examination and also my specialist training ENT I completed in Berlin at Klinikum Steglitz. I became then senior physician and leading senior physician and then in 1992 accepted the call for the Chair of Otorhinolaryngology at the Martin-Luther-University Halle-Wittenberg in Halle an der Saale. Was there then hospital director until 2003 and then I got another call to the Ludwigs-Maximilians-University in Munich and was then since 2004 Clinic Director at the Klinikum Großhadern LMU Munich. I was born in 1952 that means I am now 66 years old and that means I am retired since last year. Now I have left the clinic because I have just reached retirement age and since then I have been working in private practice in Munich where my main focus is on ear, nose and throat medicine, but especially plastic facial surgery with a focus on rhinoplasty.
3	VIKTOR: OK, well then, thank you for your intro. Now there are a total of four questionnaire blocks here, which I would go through with you, and I'll just start here with the first block. So my first question would be: What measures or tools do you use to determine the success of a treatment?
4	MR. PROF. DR. BERGHAUS: So first, of course, the clinical assessment. I look at the patient and the result of his treatment. Where it is necessary, of course, laboratory values, blood levels and so on, diagnostic imaging so clinical procedures in the first place. Of course, retrospective studies can also be done to assess and compare the results of larger groups, or to better understand the quality of a treatment method, you can also do prospective studies. I did all that in my job too.
5	VIKTOR: Ok then my follow-up question would be: To what extent do you feel it is necessary to ask patients directly for feedback in order to assess the success of the treatment.
6	MR. PROF. DR. BERGHAUS: I think that is extremely important, because the patient is the one who is at issue, and the question of how he feels after treatment is simply indispensable, I would say.
7	VIKTOR: Yes, ok, then I would be interested to know if you ever or how much you consider the health-related quality of life of your patients? So if you can not do anything with the term, I can explain it to you again briefly.
8	MR. PROF. DR. BERGHAUS: That concerns the question of the quality of life and in the end it's all about it. So this is a very important aspect and actually for the doctor just the key point. He (the doctor) brings the health-related quality of life for the patient to a high level or improved, where it is not good. And that is indeed a criterion for the success of a treatment, it may also be that one has improved the health-related quality of life by a particular treatment. So it's important, yes.
9	VIKTOR: So you already heard of these quality of life measurements, so to speak?
10	MR. PROF. DR. BERGHAUS: Yes, yes we have conducted studies like that: For example, whether patients through an ear reconstruction -if they were born without an ear, with a so-called microtia, and you make an ear to them - whether it increases the quality of life or not. And that is actually the case, it is increasing. And we studied that also for rhinoplasty and it's also increasing. In particular, if the respiratory problems are also corrected through the nose correction, so if functional and cosmetic aspects are improved. So there is a demonstrable increase in the quality of life in the patients.
11	VIKTOR: Ok, and what means did you use to measure the quality of life, I say.

12	MR. PROF. DR. BERGHAUS: There are different tools that are validated. If we remember correctly, we used the so-called "Glasgow Inventory Scale", where people are presented with questionnaires that they have to answer and these are validated questionnaires, where one can then say for sure, if there is a statistical significant positive result, then you can use that treatment. There are other questionnaires too, but I think we used this "Glasgow Inventory".
13	VIKTOR: Ok, and that was especially in your ENT departement, I suppose?
14	MR. PROF. DR. BERGHAUS: Yes, but it can be used for a variety of treatments and was then adjusted a bit for our questions.
15	VIKTOR: And do you happen to know any more of these questionnaires or tools?
16	MR. PROF. DR. BERGHAUS: Yes, so there is a "nose-score" for the functioning of the nose, whether people have discomfort with their nose and nasal breathing. I just can not break down the abbreviation that quickly, but we've also used this "nose score" to analyse the functioning of the nose and how to treat the patient.
17	VIKTOR: And did you do that on paper or electronically?
18	MR. PROF. DR. BERGHAUS: No, on paper.
19	VIKTOR: And then just after treatment or several times?
20	MR. PROF. DR. BERGHAUS: No several times to recognize a development also we have this at intervals, I think, before treatment, in a study, before treatment after treatment and then again a year later to be there long-term ... and once even yes, retrospectively, that was when we questioned people with questionnaires six, seven years after the treatments. Even over a long time, I think there was even a very small increase in satisfaction and quality of life over the longer time. We could not explain properly, but it was just like that. Sometimes that decreases in the long run again, because even if you have achieved a treatment success, it may be that after a few years, it gets a little worse. That was not so.
21	VIKTOR: Ok, so the bottom line is a positive development, at your department?
22	MR. PROF. DR. BERGHAUS: Yes.
23	VIKTOR: And what was the evaluation? So when you got the results? Was there any, was there something special? Or any complications occurred?
24	MR. PROF. DR. BERGHAUS: During treatment or evaluation?
25	VIKTOR: In the evaluation of the results.
26	MR. PROF. DR. BERGHAUS: No, not really, that went very smoothly. That's what my co-workers did. I did not do that myself. Something like this is teamwork and then there was one who did his doctoral thesis based on the whole study and he then evaluated the statistics and so on, but there was, in my memory, no special features.
27	VIKTOR: So the implementation and evaluation was uncomplicated?
28	MR. PROF. DR. BERGHAUS: Yes
29	VIKTOR: And are there any efforts within, so that question is about your time at the clinic at LMU, was there any effort to expand that further or even or even expand the area? Or was that not planned at first.
30	MR. PROF. DR. BERGHAUS: Yes, so in itself, it was already thought that we would repeat such studies again, and meanwhile other survey tools have been redesigned to capture the satisfaction of patients with nasal surgery and then you could repeat that again. Well, I'm just out of university at the moment and the likelihood is not so great that I'll pick it up again. Maybe the younger ones who are still at university.
31	VIKTOR: Ok, but there's no concrete clue that it's going to be made bigger now.
32	MR. PROF. DR. BERGHAUS: No, at the moment I would not know about it.
33	VIKTOR: Ok, I did not quite expect that you would be so well versed in the field, because that's where some of the questions I've written down here are already answered.
34	MR. PROF. DR. BERGHAUS: Yes, we did several quality of life studies. For example, we examined the gain in quality of life of patients by setting back ears. And that was also very clear that this has a positive effect.
35	VIKTOR: And yes, these measurements are always done on a relatively similar principle, I suppose?

36	MR. PROF. DR. BERGHAUS: The survey. Yes, yes, exactly
37	VIKTOR: So with standardized questionnaires or validated questionnaires.
38	MR. PROF. DR. BERGHAUS: Exactly, exactly.
39	VIKTOR: Are there certain factors that need to be considered during the measurement? So there are things to watch out for?
40	MR. PROF. DR. BERGHAUS: When questioning the patients?
41	VIKTOR: Yes
42	MR. PROF. DR. BERGHAUS: Yes, it is really important that all patients are really asked the same questions and and that they really answer that well. It's best that you actually summon one and can go through it with them personally. But then there are patients who are not up for that. If somehow, they live further away, the questionnaires are send to them. That's not ideal, then maybe they are left alone and maybe they do not understand one or the other question correctly, and then you do not really know if they've also bluntly put it to the test, but then there's the interim solution that you can talk to them by phone. So you just have to make sure that everyone understands the questions correctly and accordingly answered appropriately.
	VIKTOR: Okay, well then we've already finished the second questionnaire block and come to the next one. So the question you actually already answered to me more or less.
43	VIKTOR: So generally patient-reported patient outcomes you see as beneficial in your daily practice? I think I've heard so of you already. And also that the measurements of quality of life are useful. Or?
44	MR. PROF. DR. BERGHAUS: Yes, that's right, but I do not do it that way outside my studies in my patients' routine, frankly. So we have always done so in the context of studies and that is then a certain effort. You then have to design these surveys, you also have to ask each patient if he agrees. You have to encrypt the answers, so that the personal data are not included in the study and so on and that is also a certain effort. And maybe it would be interesting to question every patient systematically with validated questionnaires, but then there is not enough time in the daily routine. Many patients would find this strange, if you squeeze them - what the neighbors say and so on. What you typically do, what I do is to ask patients for certain key points. So I just ask my patients to find out, has brought the whole thing an advantage and then I'll do it. But when I realize the patient is totally well then it's fine too. Then I do not have to go through a complete questionnaire with them.
45	VIKTOR: Ok, it's being used in studies, but not in everyday clinical practice.
46	MR. PROF. DR. BERGHAUS: That's the way it is, yes, exactly. It is only used partially, the findings are used and not every patient is automatically a study patient, so to speak.
47	VIKTOR: So the bottom line you would say, the disadvantages still outweigh the benefits when it comes to establishing these questionnaires in clinical practice.
48	MR. PROF. DR. BERGHAUS: Yes, exactly, the effort is ultimately too big per patient in the daily routine.
49	VIKTOR: Ok, and that's just because it's too time-consuming for any patient to ask, so go through those questionnaires with them and evaluate them?
50	MR. PROF. DR. BERGHAUS: Right, and then you have to, I mean in the university clinic you're a big team and I did the interviews only partially with the patients, if they came by accident and if the patient was suitable for the study, I also gave them a questionnaire and answered that with them. But in fact, the assistants did that and took extra time in the afternoon and summoned people on certain dates, where they had free time and then they were only busy with that or calling people on the phone. And now I am alone in the practice and although I have helpers and a colleague who continues to operate next door, that's a very different situation. You have no army of assistants, which then do the tasks for you and it is already challenging just to finish your consultation hours on time. And there you have to say, there is no time for that. Nevertheless, the findings of such studies and the employment of it, helps me even now, if I want to know if my routine patient has the treatment, then I ask him the right questions to find out quickly.
51	VIKTOR: Okay, good. Are there any ideal application areas where you could imagine that it

	would even make sense to firmly establish QoL measurements or do you say that is generally difficult.
52	MR. PROF. DR. BERGHAUS: Yes, it would be nice if you could do that, but the doctor in practice simply has to do so much bureaucracy and documentation and what you have to write down for the health authorities and for legal reasons anyway. That one should think about, putting another thing on top and ask for quality of life just because of interest. And that's extra time, which is not insignificant. I think it would be important then, I mean the things that I'm doing, are already so well studied, that you know that it brings an improvement for the patient. At least, the large mass of patients. As I said rhinoplasty, ear correction. You know that. But if you have to deal with forms of treatment or therapy, where that may not be so clear, it would perhaps make sense again that as a result of such surveys you get a large number of answers as quickly as possible, which allow to say "Yes that pays off" or "Maybe you should let it go".
53	VIKTOR: Do you accidentally come across an example?
54	MR. PROF. DR. BERGHAUS: Yes, I'm just considering. Well, which one? Well, I can not think of the right one now.
55	VIKTOR: Yeah, no problem. Maybe you'll remember it later.
56	MR. PROF. DR. BERGHAUS: Yes, ok.
57	VIKTOR: Ok, but if I understand it correctly. So for clinical studies it is quite useful, but really integrating it into everyday practice is rather difficult, because it is very time consuming and the corresponding added value is then perhaps not enough to justify the implementation, so to speak.
58	MR. PROF. DR. BERGHAUS: Yes, yes.
59	VIKTOR: Ok, because there is, for example, also, there are one or several clinics, quite selected cases that have really implemented this on a regular basis, which do this with patients again and again, just to monitor the quality of treatments. So always to look "Ok, how does the satisfaction of our patients develop over the years?".
60	MR. PROF. DR. BERGHAUS: Yeah, that would make sense, but that's a lot of extra work. If you have the staff for it you... then possibly you have to procure and finance it. If you can do that, that's ok. I think there are indeed opportunities to apply at the university clinics for third party funding for such perhaps larger and longer-lasting surveys and there you can apply for third-party funding from the German Research Association. If you do that very well, you might also get money for the staff. But nowadays this has become very, very, very, very difficult for such things to get research funding. That must be very, very, very, very well founded.
61	VIKTOR: Well, then I only have a few questions left. So maybe briefly summarized by you. The big advantage of these quality of life measurements for you is that?
62	MR. PROF. DR. BERGHAUS: It means that one learns much more precisely, whether one - by reason of his treatment - does something good. Whether you really make an improvement for him or if that's not the case.
63	VIKTOR: And what would be a big drawback - so we've already talked about it a bit.
64	MR. PROF. DR. BERGHAUS: The treatment lengthens the time you spend with the patient, on the other hand, most patients appreciate it and they also see a certain signal of affection. Patients might also appreciate that, simply because you are dealing with them again. The group that would really profit from the surveys are the next groups of patients, where one draws the consequences of the interviews and then says "This does not help people at all, we will not do that anymore". So you could, for example, people with tonsillar abscesses - There are different treatment methods: You can either take out the same or just suck off the pus and leave the tonsils in it. And there it would be useful to ask such people, to ask patients how they did with the one or the other method over the long-time. And then you could also draw comparisons between the treatments. I'm not up to date right now, whether or not there is such a study, but that's a question that's not yet clear at the moment, which is the best form of treatment now. We have always taken out tonsils abscesses with the good feeling that where there is no tonsil, later no tonsil abscess can come. They are just gone. But there are others who do not do that: They only pierce the thing into the abscess and get the pus out of it. The textbooks say that this is not

	<p>the ideal treatment, but some colleagues do. It might be really interesting in the long run to find out where the bigger advantages are in the long term. Because the tonsil operation at the abscess is already the greater burden on the patient: This is then a real operation with anesthesia and in case of inflammation not very easy to operate. While just stinging in the abscess, can be performed on the examination chair when the patient is cooperative and then there the pus comes out. But that's not really enough, you have to spread the wound over and over again in the following days. Again, that's not great for the patient. That would be something that could be done with such surveys to decide what is the better method, if you recruit many, many, many patients and you are able to investigate on the in the long-term.</p>
65	<p>VIKTOR: Ok, then back to the measurements, which you did. Perhaps you can go back briefly to how that - so I have four points here - how it affected the processes, the treatment, the communication between doctor and patient and finally the health of the patients? So the first point was, how did that affect the processes at your department.</p>
66	<p>MR. PROF. DR. BERGHAUS: Well, such surveys in general, if we did something like that during nasal surgery? So, basically, these surveys have confirmed that we're actually doing it all very well and that you can easily continue like this. And just as I said, the increase in quality of life has been preserved for a long time and has even improved even further. In a study that we did in Berlin with nasal surgery and after questioning the patient satisfaction, there was something interesting: There were above average often Turkish patients - in Berlin, there are many Turks and we have then also very many Turkish patients undergo surgery. And they were above average more often not as satisfied with the result as the Germans, although we have done exactly the same operation. And there was our interpretation that perhaps in the run-up to this operation, not enough was carefully talked about with these perhaps not so well German-speaking patients. What they could expect from the operation, what outcome to expect, and where they might not be overly expectant. This may not have been discussed with the non-fluent German speaking patients carefully enough in advance. Maybe they did not ask for it and just nodded and afterwards it turned out that maybe some of them did not understand or had much higher expectations, which were not dampened in the preliminary talk. Thus, we have already drawn the conclusion that in preliminary discussions with Turkish patients in the run-up to the operation must be much more careful, we must make sure that they have understood that and also explain the risks more clearly and so on. That was a certain consequence that we drew there.</p>
67	<p>VIKTOR: So you can say that is there...</p>
68	<p>MR. PROF. DR. BERGHAUS: Yes, the other option, the interpretation was that the Turkish patients - these are all mostly young people who have received a nose correction - that may be more demanding than the Germans in terms of the result. But the study did not provide information to take that as a result. It's just a hypothesis and then we thought better "What can we do for the patients so as not to disappoint them, if it does not become 100% as they would imagine."</p>
69	<p>VIKTOR: OK so you can say that the communication is...</p>
70	<p>MR. PROF. DR. BERGHAUS: The study certainly had an impact on the results in terms of improving communication. Yes exactly.</p>
71	<p>VIKTOR: Ok, and you had already talked about processes, when you said "Yes, it's an extra effort that just happens". And in terms of treatment, they have also shown positive effects because you could just determine where you could still optimize so to speak, or what treatments, whether they really contribute to the quality of life or not.</p>
72	<p>MR. PROF. DR. BERGHAUS: Yes</p>
73	<p>VIKTOR: Okay. Then I have one more question: When you did these studies, were there any rough obstacles that you had to overcome?</p>
74	<p>MR. PROF. DR. BERGHAUS: Yes, the problem is always, especially in retrospective studies, where you have to agree with patients before you start treatment, that they are study patients. So if you're after that, it's just sometimes hard to reach those patients. They moved or something. This is such a fundamental problem and of course with foreigners the language barrier, which</p>

	one must overcome, if one interrogates the question as surely as possible, that they also understand as one thinks with the question.
75	VIKTOR: Ok, and maybe more so, what skills or resources do you think are needed to make those measurements successful?
76	MR. PROF. DR. BERGHAUS: So first you have to know the instruments really well. So let's say this "Glasgow Inventory Scale" or the "Nose Score". You have to be busy to be sure that you are using the right tools, the right questionnaires. And yes, of course, you need organizational talent in order to be able to set this up and get enough patients together within a reasonable time to be able to make a statistical statement afterwards. Of course, you can not gain anything with three patients. Since you need enough numbers, so you have to be familiar with statistics and that's the case anyway in modern medical studies anyways. If you do not control statistics, then you can not evaluate and interpret all these studies at all. So you definitely need statistic skills.
77	VIKTOR: But you would say that you have acquired the skills necessary to be able to handle such tools, or did you intend to develop your skills even further?
78	MR. PROF. DR. BERGHAUS: No, I have to be very clear here: statistics have never been my thing and I've always outsourced them, so to speak. Either one of my assistants did that, or I did, and that's what some of the assistants did, contacted the Institute for Biometrics at the university, and they have perfectly well-trained statisticians who then look at the figures or perhaps already advised in advance in the creation of the study. How best to apply it and how many people you actually have to ask now and so on. Personally, I never did that and did not learn it either and did not intend to do it again, but it was always clear to me that I would let the appropriate professionals do it. And then I just relied on them.
79	VIKTOR: And did you train employees in that direction, or did you teach staff that they could handle these tools, or how did they act?
80	MR. PROF. DR. BERGHAUS: Yes, some of them have learned that in courses that's right. Just statistics and related subjects.
81	VIKTOR: Well then we come now I believe already to the last question that would be there: For how realistic do you think is a - I say a proper, complete - implementation of such QoL measurements in the ENT area?
82	MR. PROF. DR. BERGHAUS: In the routine? So if you told the doctor in the office, you have to do it!
83	VIKTOR: Yeah or that he even says on his own "Oh I want to do that, because that has so many advantages!"
84	MR. PROF. DR. BERGHAUS: Oh, I think that's very difficult. In the university clinic, I could imagine that, because this is a center for education, every university clinic is. At the university clinic research and teaching is operated naturally, and I could at least imagine that QoL measures could be applied at certain forms of treatment and that this is even prescribed at the university clinic: That every patient who receives this or that therapy, becomes a QoL study patient and must complete questionnaires accordingly. In this case, I think that it would be feasible and there are also usually enough assistants and people who can do that then. In practice, outside of university, at the doctor's office, attending physician or so, one can do it on a voluntary basis. You might meet interested people who think it's great and may volunteer for certain diagnoses on your patients, but that will be a very small part. That will not be more than 5% of the general practitioners who will do that voluntarily. Because wherever you ask, you immediately hear that they are all overburdened in the practices. And then something extra, which is voluntary. I could imagine - however that has little chance of realization - that one says, you pay for it. Per sheet, there are 3 € or so. This can move the established (doctor), because they want to generate revenue, of course. Then the only question is, who pays?
85	VIKTOR: And do you think that applies only to the ENT area or across to other departments as well?
86	MR. PROF. DR. BERGHAUS: I think that will be more or less the same everywhere.
87	VIKTOR: Ok, thanks for that, I think we're done.

6.3 Interview with Mr. Prof. Dr. Rainer Hellweg

#	Interview
1	VIKTOR: To get started, it might be good to get a brief outline of your career so far. So you can lay that out like you want, it's just that one gets a rough idea of the expertise that you have already acquired over the years - in the medical field.
2	MR. PROF. DR. HELLWEG Ok, so I'll summarize that very briefly: I come from a humanistic high school, did there my A-Levels and studied medicine. Conducted part of the practical year at Hammersmith Hospital in London. Then after the German Armed Forces, the compulsory military service, that was still available for physicians at that time, I started in basic research at the Max Planck Institute of Psychiatry in the Department of Neurochemistry. There, I did two a half years of basic research only. Then my specialist training at the Max Planck Institute - Clinical Institute in Munich was conducted and completed. At the same time, I also worked in basic research in Martinsried and since 1991, since my specialist I am at the FU (Free University of Berlin) in Berlin. There first assistant, then senior physician and in between also acting director after leaving of the then boss and then just leading senior physician and since 2008 managing senior physician in the Charité Berlin-Mitte. I used to be in the Eschenallee, but I still have a FU-contract and now 27 years of service experience here in Berlin. And with all of us in the clinic, I think I am even the longest-serving psychiatrist, to put it this way say. I also know all areas of psychiatry. And I conduct my basic scientific research as far as possible besides the daily clinic activities, supervise doctoral students, but also have to care for inpatients and outpatients and for about 10 years I also very, very like much to write expert reports for various courts, civil courts, criminal courts with regards to psychiatric issues. That is it maybe in a nutshell.
	VIKTOR: Yes, good to know. Some of it is still new to me. So really interesting, really exciting what you've already done there. Well then I start directly with the first substantive question. And that would be:
3	VIKTOR: What measures or tools do you use to determine the success of a treatment?
4	MR. PROF. DR. HELLWEG This presupposes a knowledge or a expected value of the potential influence that one has when it comes to diseases: One has to see what can be expected, and one compares this expectation value with the actual value that one has observed in patients. I deliberately express myself in such an abstract way, because in our field of psychiatry you can hardly use scientific parameters such as blood pressure or anything like that, but there is often a very subjective perception of one's own stability of state of mind or also the mental well-being or even the emotional impairment. And then you just have to try to classify the symptoms that are mentioned by the patient, which is very subjectively presented in part, and then you finally make an evidence-based, experience-based treatment and look, "How does this patient take the treatment? Are there improvements regarding the target symptoms improvements? ". To give an example, if you have depression, you are unable to feel joy, even things that would have made you happy in the past. And then you just do an antidepressive treatment and look that in the course of time in this regard an improvement occurs, if he can then look forward to a bit to visits or when the children come to visit or something. Of course we also have measuring instruments in medicine, even in our field. This is of course questionnaire-based and there you look, whether any symptoms are still different pronounced or whether they regress and it can be judged by that. Of course, one draws on scientific literature and that's what I mean, when I talked about the expected value for comparison.
5	VIKTOR: Ok, that's where my next question comes in - that's partly what I think you already answered - and namely: To what extent do you consider it necessary to ask patients for feedback directly in order to assess the success of the treatment?
6	MR. PROF. DR. HELLWEG Yes, so I think in our field absolutely indispensable. Because it is

	<p>very treacherous in some patients that the subjective perception is different from the objective ones. And also in the so-called somatic or other medicine, I think that makes sense to catch up with the feedback of the patient. So there are certainly areas of medicine that can only be judged by measurement parameters, but the subjective feedback is actually even in oncology, in hemato-oncology, where you may measure cancer cells or the like, that's also important how the patients experience it and what attitude they have for therapy success or failure and how they handle it. That's certainly not negligible.</p>
7	<p>VIKTOR: Ok, and then there is a little further point here on the subject of health-related quality of life. Have you ever heard of this?</p>
8	<p>MR. PROF. DR. HELLWEG Yeah, that's something that has been disregarded for a long time, doctors used to rely mainly on some of the parameters and surrogate parameters to measure a therapeutic success or failure. And much more important is actually - subjectively, at least for the patient - the subjective quality of life. And one already pays attention today and tries to pay more attention to it, because - in the evaluation of therapies - "How does the quality of life of the patient change?". It does not help, as I said, that he may have fewer killer cells or tumor cells in the blood smear, but also the condition must indeed play a role: The therapy must be tolerable. Quality of life must be perceptible somewhere for the patient.</p>
9	<p>VIKTOR: And do you already have or do you know any means by which you can raise or measure the health-related quality of life?</p>
10	<p>MR. PROF. DR. HELLWEG Yes, there are various measuring instruments in quotation marks - There are mostly questionnaire-based methods that also focus on such things and in part these questionnaires are optimized for the underlying disease. So in schizophrenic patients, other things are asked for, perhaps as in depressed patients, in tumor patients, other things. So especially in recent studies, one tries to capture these parameters. So this may not be the primary therapeutic goal when developing a new therapy, but just as I said, you do not only want proof for the medical success in quotes in a study, but you also want to see how it is experienced by the patient and, if that for the quality of life of the patient is relevant.</p>
11	<p>VIKTOR: And also at your place? Have you even already carried out such measurements or questionnaires ..</p>
12	<p>MR. PROF. DR. HELLWEG Yes, yes in scientific studies. After all, I have also done dementia studies and have also been running gerontopsychiatry for a long time and that's where a lot of things play a role; not only on the patients' side, but also on the part of the relatives. "Caregiver resources" as it is called in modern German today, and in clinical practice, that's even the case when I'm doing medical consultations. That's the point that I mainly discuss. So the assistants do the day-to-day treatment and are a lot closer to the patient, but I really want to hear primarily how the patient sees himself. He does not have to be right. That is partly subjectively colored - not that we misunderstand ourselves there. But let's put it this way, patients who may be optimistic about their situation tend to be happier than the others who see more of the negative parts. And of course one tries to reinforce such things with the patient. Many do not really perceive their resources or use them at all.</p>
13	<p>VIKTOR: Ok, and are there special questionnaires that you work with? So you remember a certain one?</p>
14	<p>MR. PROF. DR. HELLWEG No, so as I said: we do not do that in everyday clinical practice. At least not with questionnaires that relate exclusively to this quality of life. But there is, for example, a very common inventory of sentiment: this is the "Becksch' Depression Inventory". Since such things are queried and these are of course information from subjects or patients. So subjective information. But in clinical practice, or when you're dealing with patients as a doctor in private practice, you're not always filling in questionnaires, but somehow you should talk directly to patients and perhaps draw their conclusions from them. It may not be as scientifically sound and it will not be reflected in any scores. This is more required in studies: In this case surveys like this come along and are examined by the study doctor including these parameters.</p>
15	<p>VIKTOR: Ok, so if I understand it correctly, then this is mostly used for studies, but not</p>

	constantly.
16	MR. PROF. DR. HELLWEG Yes not in everyday life. You have to imagine that we are already in a good situation in Germany, but the practice-based colleagues have on average only 15 minutes per patient.
17	VIKTOR: Ok, and I have some questions about the methodology of the studies you've done there. Did you do it on paper or electronically?
18	MR. PROF. DR. HELLWEG So in the past a lot of paper and now more and more electronic. That's the way it is: Studies are often multicenter studies, which are then very standardized and so-called monitors are also used to record the comparability of the data collection and earlier this was always a thick Leitz folder per subject who came together and that would be more and more electronically detected electronically today and then often checked for plausibility. So that changes a lot.
19	VIKTOR: So the subject then goes to the computer or?
20	MR. PROF. DR. HELLWEG I still did it on paper, but the idea is and of course the Charité wants to achieve that: The paperless medical record. So in the intensive care units and in surgery, it's almost paperless, I have to say. So the anaesthesiologists write hardly anything in writing. At most during the education of the patients, but everything that is given like drugs and the same, instructions, impact, everything is already entered on the screen and recorded. And its already standardized also where the buttons are and the monitoring is already integrated as well. And there is a lot going on.
21	VIKTOR: Ok, and in the studies you did there. At what interval did the interviews take place? Or in what time frame?
22	MR. PROF. DR. HELLWEG That depends on the study. So there are studies where daily visits are scheduled, sometimes weekly, sometimes monthly. So if you want to assess, for example, a therapeutic effect, it is important to see if side effects occur. Yes No. Of course you have to make visits and if you want to see long-term effects, for example, if cognitive functions improve, it is actually common that this is at least over half a year. To see if ultimately the dementia symptoms have improved. Even with schizophrenic patients one would like to know longer-term things. Actually, the studies gain in quality the longer they are done. Because then less daytime fluctuations play a role. But long-term studies are of course very, very costly and very, very expensive. So these pharmaceutical studies / admissions studies only need half a year in quotes. Because in the end it just gets very complicated. You have to order patients and follow up and and and.
23	VIKTOR: Ok, and the evaluation of the questionnaires, how did you do that?
24	MR. PROF. DR. HELLWEG In the studies, this is often done centrally so that there are no possibilities for manipulation or at least you want to reduce them. One can, of course, already manipulate the data collection, but with really good studies, the examined patient is blind to the information whether he receives a verum preparation or a placebo preparation. But even if you do small studies, maybe even to find out if it's worthwhile to go in one direction or if it's psychological research, then of course you evaluate the whole thing yourself. You always have to prove whether you, as a scientist, individually carry out a study or whether you conduct it in conjunction with others. Doing the latter, standardized evaluations are more likely to be beneficial to minimize differences in results between centers. So I also do a lot of biochemical stuff from different sources and we measure that in a laboratory, then preferably through a TA.
25	VIKTOR: Ok, TA is again?
26	MR. PROF. DR. HELLWEG Technical Assistant.
27	VIKTOR: Technical Assistant. OK.
28	MR. PROF. DR. HELLWEG Or doctoral student.
29	VIKTOR: Ok, then you already answered the question in part: So it does not look like it's planned to integrate such questionnaires into your daily routine. Have I understood that correctly?
30	MR. PROF. DR. HELLWEG So it's talked about. So, let's just say that, you can wish for a lot, but the clinical routine, the nursing staff and the doctors on station are so overloaded with

	documentation. So the problem in medicine is not that we have no money or the like. This is of course always complained, you could always like to have more money, but it is really madness what is required of documentation: for the health insurances, but also for legal protection and so on. So each additional questionnaire might not be so welcome. It would be different if, say, the patients themselves could fill something. So general feedback, if they were happy with the premises and the like. So maybe our satisfaction questionnaires are better. Regularly with our people? Well you know yourself the response rate of such things is usually very patchy. Out of 100 people you have 20 who give an answer and that's usually the people who have something to complain about. And one must say, when we lay off patients, we often do not know how it looks outside in reality. We are most likely to know this in psychiatry, because we have longer lay time and we sometimes wonder with our employees what it looks like outside. But you have to imagine, the average length of stay in the Charité is three to four days. It's not about the quality and quality of life at home. There is an order given, the patients have been patched and there is a targeted intervention and people are then dismissed quickly. In today's health care system, it really depends on efficiency. The whole thing is so-I say -thanks to industrialization.
31	VIKTOR: Ok, then we come to the next block of questions. Actually, you have already addressed a little something of what I wanted to ask. If you could give an example of using such questionnaires, could you name one? So maybe you can name one more. Just a study you did. I do not know, just one that you remember.
32	MR. PROF. DR. HELLWEG So well, for example, in field studies where the activities of daily living are regularly recorded, it does not help to find a neuropsychological problem and then perhaps find that the deterioration of neurocognitive functions is delayed by dementia patients, but one would also like to know how people's everyday activities are. Whether they are just making progress or no further deterioration. That would be something like that, for example. Then you have to look, if our cultures are normalized as well, and so on. There is a lot of work.
33	VIKTOR: Yeah, ok, you pass over perfectly to my next point. Namely: What are the factors that must be taken into account in such a measurement in any case?
34	MR. PROF. DR. HELLWEG So gender must be considered, age must be considered, cultural background and what is not to be underestimated, the level of education: So you can wonderfully manipulate study results by unpacking uneducated people in the control groups with many comorbidities. And then you have a great success in the verum group, but then that has nothing specific to do with the verum, but that's a sampling bias: the study groups, which are not well stratified, are not well-randomized, are not balanced. So there are standardized questionnaires in English, but they are not validated at all for the specific culture.
35	VIKTOR: Okay, you also mentioned some factors that are more related to statistics. So properly randomized, did you say is important.
36	MR. PROF. DR. HELLWEG Yes, that's important. To compare the groups in terms of socioeconomic and educational parameters, athletic activity, there are very many things. Whether someone is non-smoker. Yes, whether it has leisure activities. Whether there is athletic activity. There are many criteria regarding the studies. These are all well-known parameters, depending on how often I do my studies. And I'm not even talking about genetic differences. So Asians, for example, have very different genetic characteristics of some enzymes in liver metabolism and tolerate foods quite differently and and and. This is very problematic if you take control groups from Asia and compare them with other groups from Europe, for example, or vice versa. This is usually not comparable. Yes, there are genetic factors that simplify the results, sometimes you know them, mostly you do not know them and when you know them you have to make sure in studies that it is very comparable. So in dementia, I know very well and there is such an Apo4 polymorphism (apolipoprotein E4 polymorphism), which is completely different in northern Europe, as in southern Europe. So if I want to manipulate study results in Southern Europe, I would have to compare many people from Spain and Portugal with Finns or with Scandinavians. I always get differences out there. That's that, but that's the genetic background.

37	VIKTOR: Ok, interesting! Exactly matching: Are there still factors that then play a role in the evaluation at the end. So when you collect the questionnaires again at the end?
38	MR. PROF. DR. HELLWEG Yes, there is - very, very important - missing data. It is important in association studies that you get all the data you want together. There are always volunteers who do not come or break out of the study or the specialist who is supposed to make the visit is sick or an appointment is postponed and so on. So you get so many variances just through the everyday life. The monitors try to homogenize this, but the question is always how to deal with the missing data and there are different methods: For example, the "basic forward observation procedure". You have twelve remaining collection times, the patient only stays up to the sixth, and then you take the sixth point you have on the top and continue to calculate it for the six remaining visit points. That is very critical. Or they say they have a drop-out, but in part they come down to much smaller numbers of people who completed the study. So small numbers are generally critical in scientific studies. So many study results have the problem that they are not completely carried out to the end; that the conclusions may be drawn from only 10% of the originally enrolled subjects. But that is just one of the scientific subtleties that could subsequently be problematic in research.
39	VIKTOR: OK, here we come to the next block of topics. It's just a bit like the experiences that you've made. Actually, you already mentioned some of that. So you would say that the treatment outcomes reported to you by patients are useful in your practice - so in your day-to-day work practice?
40	MR. PROF. DR. HELLWEG Absolutely, absolutely, so I always ask for effect and side effect. This is a very important point to find out if the patient, how he ultimately experienced a drug or therapeutic success - or therapeutic action, but can also be a drug - and what it triggers in him. That does not mean that (the perception of the patient) must be objectively right, but his subjective interpretation is indeed decisive for the therapy success. Yes, because when a person feels healthy or ill, it has to do with how he personally experiences it.
41	VIKTOR: Ok, and with this health-related quality of life or quality of life is that similar I suppose?
42	MR. PROF. DR. HELLWEG Yes absolutely! Yes, that's why these parameters are so important. What is considered today as a quality of life is very individual, very different. I always like to bring the fairy tale of Hans in Luck, who after a year's work in a foreign country keeps exchanging his wages and in the end he has a rock in his arms and then he exchanges this one and then goes completely carelessly and feels free. He then goes back without pay to the village, but subjectively, he is Hans in luck. Yes you could say he was a bad businessman, he was stupid. That's the way you would say today, you would actually have to refer him to psychiatry, because he can not handle money. But subjectively Hans considers himself lucky. And that's why the evaluation mechanisms, such as automatic thoughts or the basic assumptions of a patient to assess the quality of life are very important.
43	VIKTOR: Ok, good. Then there is another question. Exactly, you have already said that properly in everyday life these quality of life or life quality measurements cannot be permanent or are not used permanently.
44	MR. PROF. DR. HELLWEG Yes, we have not used it yet. You ask for it and it goes in with the other reviews. So if you look at therapy success, for example, you also ask everyday relevance, but that's why it does not necessarily have this quality of life surveys in it. But in studies, especially when they run multicentric, this is increasingly demanded today. Because you just do not want to have a drug which, as I said, helps to improve a biomarker or any medical parameter, but you also want to know what kind of effect it has on QoL. As far as the theory goes, practice often looks different. In cancer therapy then drugs are approved, which may allow survival for 3-4 days compared to the other treatment and there is always the question of whether this is really worth it for the quality of life. There may also be side effects.
45	VIKTOR: Yes, yes, and what would be the main reasons from your perspective that you have not yet firmly established that?
46	MR. PROF. DR. HELLWEG The time, the time. We already have too much bureaucracy in

	<p>medical treatment. That concerns all service areas. This is not much different with banks. If a banker wants to sell you something, then he must also keep a record of how he has educated you and pointed out risks. And so we are in medicine too. We are increasingly challenged to just document our achievements and secure ourselves, educate patients and identify risks and the like. And perhaps this will be more often the case when you use computers now, that you later click on the screen with some pen during the patient talk and encode any items there. Yes, I do not know if that would happen, but since today all people hang out on the smartphone, that's normal, that you no longer look the others in the eyes and talk face to face, but to play somewhere in any electronic devices or something similar. One does not know. It may be that this will change culturally.</p>
47	<p>VIKTOR: Ok, and you would say, you see inside your organization a need to measure health-related LQ?</p>
48	<p>MR. PROF. DR. HELLWEG The need is there, but I do not necessarily see a shortage of related instruments. So, if you want to measure LQ, it actually exists for every glitch. So there you can certainly develop new scales, but you should perhaps norm or investigate the existing scales even more with respect to these confounders. This is just very laborious. Well, I have named some things and there are relatively few good examinations yes? Yes, for example, if we correct that with the grades of education and if there would be different results with regard to the different degrees of education. I would guess so and then the question is how to interpret it. Yes, the question is, what is the expectation of quality of life and how is LQ individually defined.</p>
49	<p>VIKTOR: Ok, and what do you think are reasons for doctors in general, so I'm not just saying in the psychiatric field, not to perform these LQ measurements?</p>
50	<p>MR. PROF. DR. HELLWEG So they all would like to do that, so out of inner conviction. Why this does not happen is simply the time management and simply the missing time. And I would find it problematic if even more bureaucracy would come in at the expense of a direct individual doctor-patient conversation. The last one is paid little or not remunerated at all and that is actually what the patients expect. They do not necessarily expect a quality of life questionnaire, but an individual interview, but that may be my outdated view. Nowadays, the mainstream is a different one, of course one would like to sell such questionnaires and then it can be computerized, but I do not know if we do it such a big favour this way. Because we are not pure machines.</p>
51	<p>VIKTOR: Yes, that is to be hoped.</p>
52	<p>MR. PROF. DR. HELLWEG Yes.</p>
53	<p>VIKTOR: Exactly, so you already have actually anticipated it already, but maybe you can say again briefly, what would be for you the most important advantages of a solid implementation of this quality of life measurement.</p>
54	<p>MR. PROF. DR. HELLWEG Yes, the advantage would be that one can compare treatment courses and treatment courses better pre-post. That one can compare what has been the initial state, what has been the initial state and what is after measure X, then the result Y. So that would be helpful. And that perhaps you can better optimize your own therapies and maybe even improve them and then compare them.</p>
55	<p>VIKTOR: And the most important disadvantage, would probably still be that you have the problem with the bureaucracy and the extra time.</p>
56	<p>MR. PROF. DR. HELLWEG Yes, exactly. Exactly right.</p>
57	<p>VIKTOR: Ok, so here are some questions about how the measurements you made in the studies. How they impacted on the processes or the treatment. Or more generally, how the impact of the impact of the study's results has affected your work.</p>
58	<p>MR. PROF. DR. HELLWEG Yes, so if the study results actually suggest or show a positive effect in quality of life, then this is also a selling point for this type of therapy. In other words, that's very good when a therapy X shows an improvement in quality of life. That's a correlation. Often we do not know enough about the mechanisms, but that is certainly a good argument for this, and so, in more recent studies, care is taken to see whether there is an improvement in the</p>

	quality of life. This is actually a requirement for the forms of therapy and the therapies that are being asked today. This requires quantification measures.
59	VIKTOR: And would you say communication between doctor and patient has improved through these studies. Can you say that?
60	MR. PROF. DR. HELLWEG I would say so, at least theoretically, because I still assume that it works without such studies and there are doctors who are also able to talk to patients, but by the fact that something like this is also observed will perhaps lead to the fact that something like quality of life will get more attention also in the 0815 (basic) therapy
61	VIKTOR: Ok, then I would be interested in the questionnaire, if there were any obstacles you had when you were doing the studies. Any difficulties you had.
62	MR. PROF. DR. HELLWEG There are two obstacle groups. One is the Commission, which also can act very differently: On one hand, the commissions, I say, that have a basic attitude that encourages research and the commissions, which primarily have the goal of making any kind of research impossible. That is very, very different: from state to state or district to district, from country to country and so on. And the next obstacle is, of course, the big issue of privacy. So the things that are then medically analyzed. It used to be enough to just have a Leitz folder somewhere and lock it up in an inaccessible room. So that's getting more and more difficult now. Where on which electronic data carriers with which security measures such patient-related, study-related data may be stored. This is certainly not conducive to the conduct of studies, but it certainly has its legal and clinical-legal implications. Let's put it this way.
63	VIKTOR: Just recently, that has just increased a lot.
64	MR. PROF. DR. HELLWEG Right.
65	VIKTOR: Ok and what do you think, from where should such an impulse go out, that one says "Ok, we are conducting these surveys now really on a daily or fixed basis."?
66	MR. PROF. DR. HELLWEG Well usually it is about money. So if the health insurance companies would promote such a thing, I could imagine that like now in the dementia treatment it is also already expected from the established doctor that he occasionally records the cognitive status. I am just skeptical or I would like to warn against any kind of action, which of course is always gladly implemented, but which are ultimately meaningless. Which simply generate on paper or on-screen surrogate parameters because it is outward opportunistic or perhaps even required. So the relationship between the doctor and the patient is always decisive. This explains a large part of the variance of therapy success and if (...). So a questionnaire certainly does not replace, let's say, a medical competence.
67	VIKTOR: Ok, then we come to the last question block. This is a bit about the resources and skills needed to do such studies. In your opinion, what would be the most important skills or even the resources you need to be able to do this?
68	MR. PROF. DR. HELLWEG That's very, very general now. So the most expensive is always the manpower. So staff is the most expensive, to put it that way. Then the next point is that you would then also have to do a training dealing with these instruments - so that these instruments are used and interpreted evenly and comparably. This can be very time-consuming: Especially in our field, there are very complicated questionnaires, for example in schizophrenia. These are very extensive questions and then you have to interpret the questions and the forms of therapy, delta X compared to delta Y, and there may well be differences. And of course you have to train the rater so that there is comparable data. That also plays along with personnel.
69	VIKTOR: Ok, well, you have anticipated another question for me. Since I would have asked now about the staff and how they have to be trained, but you have already said that. Ok, then I would only be interested in whether in the future there is somehow planned to take hold even more intense on such questionnaires and expand the use even further or?
70	MR. PROF. DR. HELLWEG That can be. But then perhaps this is the case in medical sociology or in medical health sciences, where such general things are at stake. And of course you can do that in the operational subjects as well - that's also important, because it's not just about making an operation look good or succeeding, but of course you also want to know how

	people live afterwards. So what can he do with the operating result? I think there is certainly a need there, but then you have to always specialize in the disease and make it applicable.
71	VIKTOR: Ok, so you would consider a really complete integration of these QoL measurements to be realistic in the clinic or practice life? Can you say that?
72	MR. PROF. DR. HELLWEG Not realistic, but desirable. And it only becomes realistic when, say, we are socialized with the appropriate resources, which then have to be there. What I would not find so great would be if this leads to less direct contact between the doctor and the patient or only led to even more administrative and bureaucracy and documentation costs are generated at the expense of the nursing staff and at the expense of the doctors.
73	VIKTOR: Yeah, well then I think we're so far through, thank you again very, very cordially.
74	MR. PROF. DR. HELLWEG Great, then good luck!
75	VIKTOR: Thank you, thank you!

6.4 Interview with Mr. Dr. Alexander Limburg

#	Interview
1	VIKTOR: Well, then I'll just start now. First question would be, first of all, that I would ask you to introduce yourself very briefly. Just to illuminate your career. So that one knows, which competence you have already acquired.
2	MR. DR. LIMBURG: Ok, so I'm born in 1951 and grew up in a family of doctors. And then I decided to study medicine. I had the big advantage to make my A-Levels in the Saarland - that is German-French. Then I studied medicine in Belgium and then I returned to Germany. Did preliminary examination in Germany and then switched to Munich after the preliminary examination. I also did a state examination here. Then actually a very simple CV in the sense of specialist training in gynaecology at the University Hospital from 1980 to 1988 and then 1988 November, so now exactly 30 years ago, then led a private practice. And that's a bit of my lifetime as a gynaecologist.
3	VIKTOR: Ok, cool. So thank you very much for this intro. Then we come to the first of four thematic blocks and each block has about 5 questions. So, the first question from the first topic block would be: What measures or tools do you use to determine the success of a treatment?
4	MR. DR. LIMBURG: Which tools do I use?
5	VIKTOR: Or measures yes.
6	MR. DR. LIMBURG: So now generally tools / measures for a medical diagnosis?
7	VIKTOR: Exactly how you sort of determine if your treatment was successful or not.
8	MR. DR. LIMBURG: Ok, well, first you have to have the basic knowledge. The basic knowledge consists of an exact analysis of the patients in terms of their medical history. There is the motto: "a good medical history is half the diagnosis". The other is, of course, what you learn in the course of your life years. You draw on the framework of your experience. The third is, of course, the technical competence that you simply have to acquire by yourself. Fourth, the human competence that you really cannot really learn. I'll just say that you have it or you don't. It is very, very difficult. There are many who think they have to do medicine but do not have human qualities or abilities in human interaction. That's why medicine is always something I think should be very human because we have one person and not something else. Yes, the other is, of course, when you have done your diagnostics, that you check them through feedback. Was it right, was it wrong? The next thing is that I say, "It's important to make a diagnosis in medicine, even if you're wrong." But the most important thing is that they also taught me at the university is to say "Okay, that's the diagnosis it for me and that's it". So do not make wishy-washy medicine, but instead be sovereign in your diagnosis and in your therapeutic approaches.
9	VIKTOR: Ok, ok. That's the next question. You just mentioned it a bit. In terms of feedback: How is it necessary in your everyday life, in your practice, to ask patients directly for feedback in order to determine the success of a treatment?

10	MR. DR. LIMBURG: That's extremely important. So I get not only the feedback from the patients, but also from the clinics. Of course, I also believe that the success you have, you realize through the patient that says: "You were right in your diagnostics.". And if that's true, you also have this patient - I'll put it in quotes – for the rest of his life.
11	VIKTOR: Ok, then the next question in the topic block would be: First of all, if you have ever heard of the health-related quality of life?
12	MR. DR. LIMBURG: I did not understand that health -?
13	VIKTOR: Health-related quality of life.
14	MR. DR. LIMBURG: Yes, of course. I am one of the few gynaecologists to do breast diagnostics. This has now largely passed into the hands of radiologists and I have of my 1000 patients certainly 150, where I look after the aftercare and there are also quite people who say of themselves, they do not want to be treated in the case of breast cancer. Right now, I have a patient like that, I'm just saying this as an digression, she's 86 years old, has a recurrence of breast cancer, but at the same time has back surgery and does not want to be treated, and for her the path of her quality of life is to do no diagnostics and no therapy at the moment because they would probably burden too much in the grand total. And that's something you have to learn as a doctor. That one says: "The quality of life is actually the highest good, which one can give to the patient". And what you have to weigh: In how far do you go along with decision of the patient and where does it stop? This is a situation where you might get in conflict situations with your own professional ethic, which is the desire to help the patient. But the ultimate good is ultimately that of the patient. If he wants and is able to dispose of his own body, then one has to respect that as a doctor. Under quality of life I understand - for a doctor - the respect towards the patient. That means he determines the quality of life, not the doctor! I can show ways to improve its quality. Whether or not he wants to go that way is always the patient's decision.
15	VIKTOR: OK, so from your response, I take it that you think it's important to evaluate and consider the quality of life of your patients. Right?
16	MR. DR. LIMBURG: Yes, that's one of the most important things we have and if you do not internalize that quality of life, then you certainly are not a good doctor, I would say so.
17	VIKTOR: Ok and how do you measure the quality of life or how do you try to determine it?
18	MR. DR. LIMBURG: Quality of life can only be measured by the behaviour of the patient towards yourself. If he senses that you have a different path or understanding of quality, he would probably leave you.
19	VIKTOR: So then you do that ...?
20	MR. DR. LIMBURG: So the bonding with the patient is in my opinion important, but of course as a doctor you should not bend over backwards. But also, the patient does not have to bend over backwards and quality of life is ultimately - how can I say? We are helping professions. Quality of life stands for the patient. The patient is not interested in whether I feel well or not in the treatment, but it is about his life and his quality and not mine.
21	VIKTOR: Yeah, well then you just determine that based on the communication between you and the patient?
22	MR. DR. LIMBURG: Right, that's right.
23	VIKTOR: I mean there are also - I do not know - questionnaires or similar, but you do not make use of that?
24	MR. DR. LIMBURG: No, because the patient answers the questionnaire in my conversation. And my interview is the questionnaire and if the patient stays with me, then the questionnaire is answered.
25	VIKTOR: Ok, but is there a questionnaire that you use as a template or?
26	MR. DR. LIMBURG: No, I'm making that out of instinct. It might be good if there was such a thing - I say. But that's relatively difficult, I think, because it's something that goes into the interaction of the doctor-patient relationship. And that's what I said at the beginning: Many things can be learned, but humanity, you may have it or you don't. And there you have to do a lot of things intuitively, because this way you will gain the trust of the patient.
27	VIKTOR: Yes, ok. So now I can be a bit more specific. So what my topic is concerned. So it's

	roughly about the following: There is the idea to carry out such quality of life measurements permanently so that patients regularly have to complete such questionnaires in order to be able to collect this quality of life.
28	MR. DR. LIMBURG: To be able to validate the quality of life, ok.
29	VIKTOR: Exactly, and now I just have to check off a few points here. So from what I've heard so far, it does not look as if you're planning to permanently introduce such questionnaires. Right?
30	MR. DR. LIMBURG: Yes, of course, I am also at the end of my career and would not do that, but in principle I would say for a medicine of the future, which is in a way - I'll say that very harshly - inhumane, It might be important to attach importance to these things especially because we have more physicians who are likely to have less human intuition than those from the older generation. I say that harshly. I believe that many who have a top-notch high school diploma may not have the human skills and do not have social skills like the others, who were not so good at certain subjects or in their A-levels, but just have a good identification and a good knowledge of human nature from their upbringing. So, it's perfectly fine now that deficits are emerging on the one hand just by the selection - I do not want to say negative selection right now - but maybe by a selection of students who have less competence in the human side. Maybe they have an incredibly good gift in terms of memorization or maybe even technical, but that's why it's even more important that such quality of life statistics be held or questions are asked. And that this is quasi questioned by the patient and also by the doctor.
31	VIKTOR: Ok so thank you already for the input. Then we come to the second theme block.
	VIKTOR: And it's a bit of a question of how you would categorize this quality of life topic. So let's say you want to do such a permanent quality of life measurement implementation. How would you tackle that? So maybe you think of something?
32	MR. DR. LIMBURG: Ok, a question or counter question on my part: We are talking about quality of life from the patient?
33	VIKTOR: Right, yes.
34	MR. DR. LIMBURG: So we do not talk about the quality of life from the doctor?
35	VIKTOR: Right.
36	MR. DR. LIMBURG: Hahaha ok, that's another topic. Well. I would say that this topic is extremely complex, because what is quality? The quality of life, what the individual understands by quality of life is very diverse. One person understands more quality when he says he eats well, he travels a lot, he has a lot of money. The next one says: "For me is the most important thing to be healthy". The next one says:" I want to have domestic happiness". The next but one says for him it is important to play a good social role. The next one says I like...whatever. So quality of life is extremely variable or anyone can define only for themselves, what he understands by quality. May I perhaps ask a counter question?
37	VIKTOR: Yes.
38	MR. DR. LIMBURG: How do you explain quality? What is quality? Where is the weighting of the quality?
39	VIKTOR: OK, I can briefly read you the official definition that would be there: In health care, health-related quality of life or quality of life is an assessment of the patient, about how the individual's well-being is affected over time by an illness, disability or disorder. Health-related quality of life covers the status of psychological, physical, functional and social health.
40	MR. DR. LIMBURG: What was that? Mentally, physically?
41	VIKTOR: Functional and social.
42	MR. DR. LIMBURG: Okay, so first of all, that is just one concept of quality. Because that only refers to illness. But medicine has others - medicine is not just disease. Medicine is as well as precaution or aftercare. So there I would - I do not want to say question - but still split the concept of the quality of life in the diction, as you have just brought it. You have only brought one concept here - the quality of life is in your question only related to the disease. So and now I can on these points... to this point I can comment, but I just want to say the normal quality of life is not only related to disease, but quality of life means also status of health or how do I

	maintain my health. This is just as much a position of quality of life. If this is defined differently for you, I only comment on the disease aspect.
43	VIKTOR: So that's actually part of it. As I said, there are several dimensions of health, that is, social, physical, psychological.
44	MR. DR. LIMBURG: Right, but you said: "Health in life restricts physical, mental, functional and social health." And in this context, the question is put with focus on disease. Is that correct?
45	VIKTOR: Partially.
46	MR. DR. LIMBURG: That was your definition. So you said "through illness". I wrote it down.
47	VIKTOR: Yes. It is an assessment of how the individual's well-being is affected over time by a disease, disability, or disorder.
48	MR. DR. LIMBURG: Yes, exactly. So that's exactly what I allude to. Illness, disability, disorder. This is all in terms of the big negative above and not the positive, and that's why I would say that in terms of subject matter this is just one point of the quality of life. There is another point of quality of life. This is the maintenance of quality and it starts even before the disease.
49	VIKTOR: Sorry, what point did you just mention? That did not really come in.
50	MR. DR. LIMBURG: I say: The quality of life does not start with an illness, disturbance of well-being or whatever, but also in the maintenance of health. That is just the condition that is actually there before an illness. So if you say the generic term "Quality of Life", then I would make an arrow down to the left and say, "This is quality of life under the aspect of illness, under the aspect of disability and so on". And an arrow to the right, which says: "These are prospective measures for the preservation of the quality of life in the sense of precaution in medicine".
51	VIKTOR: Ok, so ...
52	MR. DR. LIMBURG: So, what you're saying now, " I'm investigating Quality of Life" and you're referring to illness and disorder, and so on, that's one understanding of the concept of quality of life. OK? Maybe that's a bit annoying now, but keep going. What is the next question?
53	VIKTOR: The next question would be if you could imagine an example where it would make sense to permanently insert such questionnaires where patients are asked how they feel in terms of - as I said - physical, mental, functional and social aspects of their Health?
54	MR. DR. LIMBURG: Well, I think that would make sense, for example with cancer. It makes perfect sense. I would think it nonsensical for example - I am a gynecologist - In case of pregnancy. Because pregnancy is not a disease. Of course you could ask, "How are you doing with the child now?" Or "How was your birth?" Or whatever But that's exactly the difference I've made in terms of disease and maintenance of health, as far as quality of life is concerned. You could also develop a questionnaire where you ask, "How did your pregnancy go?", "Were you happy with the delivery?", "How are you doing with the child?", "Are there changes in your marriage?" and so on and so on. But that would be something that is not related to disease, but to health. That's just as interesting, but still under the generic term of quality of life.
55	VIKTOR: Ok, yes I like that. Then the next question would be which factors to consider if you want to make such measurements?
56	MR. DR. LIMBURG: You mean which factors? So yes. The question should of course be in way that... Yes, that is difficult. Of course, you should try somehow to validate whether the care of a cancer patient went well in terms of the clinic, the doctor, in the psychosocial area, in the aftercare. Whether they are psychosocially cared for, whether they have problems in their marriage and so and so on. So I think that would make sense here to produce a validation in order to possibly generate process optimizations. So it's about the question of an algorithm. The question is, how do we find forms that bring you in one direction, which brings the patient in one direction to make a statement about whether they are satisfied or dissatisfied to put it in a nutshell.
57	VIKTOR: Okay, let's get to the third of four questionnaires.
	VIKTOR: I'll just summarize what you just said so far. So in general, would you say that

	patient-reported outcomes benefit your daily practice? right?
58	MR. DR. LIMBURG: Well, I'm saying, of course, they're useful in the sense that we can quasi see patient satisfaction. Now let's assume in practice the so-called QM, i.e. quality management. There are even patient surveys described in it and unfortunately, we have everything in our books of course, but honestly never really practiced, because the patients vote ultimately with their feet. And if we notice or if I notice from 100 cancer patients one may jump off, then I say to myself: "Well with that one it did not work out now, but in sum, if 99 stay with me, then I practice a proper medicine ". I'll say it boldly now. But I mean for certain authorities... Or do you know as a single practice you are a market that depends on the patients. Surely such surveys are extremely important for institutions that more or less totally do not care whether there are more or fewer patients. For them it may be much more important to know why patients come to your clinic or ambulance or why this and that does not happen or why there are migrations. Because they do not even know why that happens. Maybe because the patient X has seen another assistant with his laryngeal carcinoma in the aftercare seven times. For example. Something like that does not happen to me in practice, because the patients are only with me. So, for me the ratings in the individual practice are completely different. I can see that because the patient is not coming anymore. If the patient does not come back then he was dissatisfied in some way and then I still have the options to call him and ask, what did not fit? So, I have a direct, manageable way, which is much, much easier in individual practice, as in an institution such as in a clinic or a medical care center or a large institution. These must certainly do other surveys, as I have to do this in my own practice, because I have a direct line. I know who is coming and who is not coming. This is manageable.
59	VIKTOR: Ok, well, then, one main reason you would not permanently introduce such questionnaires would be the fact that your patients are more or less voting through their feet, and you are already aware of whether your methods are virtually successful or not?
60	MR. DR. LIMBURG: Exactly. And when I realize one is not coming, who I really care about... If I have patients I know for 15 years, who have a cancer and suddenly do not come anymore. I even have a system to find that out. So either they died. Then I have a phone number or get a death notice. Or they were often dissatisfied and it is very important to me of course to find that out - I'll tell it now between you and me - perhaps my receptionist was outrageous or has not given an appointment. That's extremely important to me. But I can do that in a small informal way and do not need a questionnaire. Since I can ask my girls in front: "Why did Ms. Mayer not come actually? Do you have an idea for this? "" No, no idea ". Well, then I'll just give her call. Just like that and then I will find it out. And then she says yes, she broke her leg. Yeah well, then it's clear, then she will not come for half a year. But I also have a so-called feedback system myself, which I control and check myself.
61	VIKTOR: Ok, so now you do not see any need for ...
62	MR. DR. LIMBURG: In individual practice, no. If it were bigger institutions, it would be extremely important. Because I want to say it the other way around: From the lack of such surveys benefits the individual practice. What do you think why so many people with carcinomas go into individual practice? Because they have a single contact person here who cares about them for decades, and in the clinic they are mass products. Do you understand?
63	VIKTOR: Yes, ok. Well, then I would like to know again, what would be the biggest advantages of such an implementation for you? So from such questionnaires on a permanent basis?
64	MR. DR. LIMBURG: So a questionnaire would be - so from my point of view, I have told you that I do not necessarily need a questionnaire - but I say now generally for larger institutions, institutes, outpatient clinics, MVZ's and so on this is something extremely important for patient loyalty. And then the quality is also evaluated by patients and then according to the feedback, hospital management or a medical supervisor can draw conclusions about what can be improved in the system.
65	VIKTOR: Ok, and what would be some relevant disadvantages of such an implementation for you?

66	MR. DR. LIMBURG: Nothing at all.
67	VIKTOR: Nothing at all?
68	MR. DR. LIMBURG: No.
69	VIKTOR: Ok.
70	MR. DR. LIMBURG: So, everything in life, which serves a quality improvement, the patient, as well as the entire care, care processes, perhaps also a skilful time management, etc. makes sense. I think nobody should resist it.
71	VIKTOR: Ok, but maybe you still come up against any obstacles that might come back to you if you were to try something like that on a permanent basis in hospitals or in practice?
72	MR. DR. LIMBURG: Yes. I think what might not be so easy is to tell patients why they should do it. Obviously, one has to emphasize that it's about improving care, optimizing care, and that's what it really needs to be. So, one would have to invite the patient - in quotes - to such a survey or ask for help in order to bring process-oriented results, which then also lead to improvements for themselves after a certain algorithm. It can also be that someone is completely satisfied, then he will grade everything with a 1 (Note: 1 is the best grade in Germany) and then of course you can do nothing with the survey. If everything is very good or very bad then it will always be very difficult. And a questionnaire has to... if you do something like that, and I see a greater difficulty... So, the biggest difficulty I see in asking questions, is that they are result-oriented on the one hand, but of course you can always postulate a certain answer in the question and that is a very, very difficult question. The hardest question is: how do you ask the questions?
73	VIKTOR: Ok
74	MR. DR. LIMBURG: And that's always... You can... How should I say? There is already pre-selection by the question. So, to keep the question so neutral that you get a result, which makes sense. That's the art. This is something that may need to be decided by others, sociologists, or so, or semantics, linguists. But that can be manipulated the most today. That happens too. You can only ask a question positively or negatively: "Were you satisfied" or "Were you dissatisfied?". Then you already have differences in the selection. And that's it. When creating questionnaires, keep them in such a way that really results in a good, a statement that is evaluable, that is usable.
75	VIKTOR: Yes, ok. Good point.
76	MR. DR. LIMBURG: This is something that I do not see as a negative point, but where I just see a difficulty. This is also called "post-hypothesis statistics", do you understand? So, you can set up a test hypothesis and can be so manipulative in your question that you get the result, what any one wants to have. And there's the difficulty in that just to stay neutral. That's all I wanted to say. Ok next point.
77	VIKTOR: Ok, then we come to the last block of topics, because I would be interested in what you believe, what skills or resources would be necessary to establish such measures or to implement them successfully. You've already touched it a bit, but you may come up with some other skills or resources you need.
78	MR. DR. LIMBURG: Well, you need smart people. You need extremely clever minds, which steer in a positive direction what you collect in terms of data. So it's not just about collecting data. This is done on every corner today. But it's about analysing the data in such a way that ultimately something comes out for the patient. Quasi in terms of a more effective treatment, better management, time reduction, better aftercare and so on. Then a process optimization is also achieved as a whole. Each form of a questionnaire should aim to optimize the system. And that can also be done, if so to speak, those who then finally evaluate that can virtually transform that into a positivity or a change in the system. So the question or the result is not decisive, but the decisive thing is what will be improved.
79	VIKTOR: That then you really draw conclusions from what you have measured?
80	MR. DR. LIMBURG: Right, and that the improvement will be implemented. There are so many suggestions for improving systems, but nothing happens. It always hangs on to it. And I always say that and that's why so many people always say, they do not even take part in surveys

	anymore, because they're so done with it because they see that polls are being surveyed, but nothing changes in the process. There is frustration in the population. You can see that on many things. You can see that easily through people voting AFD (<i>Note: A right wing party in Germany called "Alternative für Deutschland"</i>). We do not have to put medicine in the foreground. When it comes to the question of process optimization, then there are analyses and we have enough analysis, but in the end, there is suddenly a new party. Then you can ask yourself the question, why did this condition emerge? If I compare the entire health care system with politics, there probably have been some failures as well because some mistakes in politics were not transformed into new processes to prevent this. Yes? So maybe the digression is a bit far now, but I think that's pretty much the same everywhere. Not only in medicine. So when it comes to surveys or optimization of actions. Yes, it's about controlling, right? Yes, it is about what is controlled and also what you want to introduce to improve measure for sure.
81	VIKTOR: Yeah, so I definitely understand what you are referring to with the comparison.
82	MR. DR. LIMBURG: Good.
83	VIKTOR: Yes, then the last two, three questions are probably done more or less. It's about whether you'd like to learn more skills to implement such questionnaires, but what you've said it is rather unlikely?
84	MR. DR. LIMBURG: So each questionnaire, which in practice... If there are only five questions in the header and five answers and you have to implement something in a quality management for your own practice, then of course you will certainly have its positive - maybe there are also things, when you ask "how is the waiting time in practice?" or "Did he take enough time?" because you might not get a 1, but a 2. Alright. But I would say for a quality management monitoring your own practice, also makes sense in the small practice - My God small practice, I have 250 patients in the quarter it is not just a little - makes something like this sense. But in the context of this quality management, which is actually already prescribed. So actually, such patient surveys in our quality management are already implemented and prescribed, but no one does it.
85	VIKTOR: Well it will not be like ...
86	MR. DR. LIMBURG: It is not lived.
87	VIKTOR: Not lived and not punished if you do not do that.
88	MR. DR. LIMBURG: Of course not. No. Anyone can do as he pleases. As I said earlier, the patient is voting with his feet. If you see 100 cancer patients, maybe one jumps off, then you might say, "Well, that's in some special area, maybe something did not fit." But let's just say, if 40 dropped off, we'd probably issue a questionnaire to find out why. But if most people stick to you anyway, that's okay, then it seems to be alright in sum. But in principle, I would say, if that's a questionnaire with five questions and corresponding ratings from one to five, that's certainly not bad for bringing QM to life and for validation. So I would not resist or say "That's nonsense!". No. It can always be argued that it is about implementing an improvement in care or whatever.
89	VIKTOR: And is it also feasible from the organizational effort?
90	MR. DR. LIMBURG: Because people always wait 10, 15, 20 minutes anyway. Then they will get such a questionnaire and then you can say: "We have a questionnaire here to check our quality management. Please help us and throw this note in our box. I think in this way, many would join in.
91	VIKTOR: Okay, then to the last questions. I would have to check this off now: Do you intend to or do you intend to take specific measures to establish or expand such quality of life measurements?
92	MR. DR. LIMBURG: Well, at the moment I have not planned it, but if there are suggestions from outside, I would not refuse.
93	VIKTOR: Ok and accordingly the next question: Do you plan to train staff in this area?
94	MR. DR. LIMBURG: They are already trained. And training, if there were additional training, there are also trainings from the KV (<i>Note: Official German Medical Association</i>), in this direction anyway. This is already implemented, but if there was an extra thing, it would

	certainly not be bad, as it serves only the operation or the quality management for the patient.
95	VIKTOR: Cool, yes, that was the last question. Then we are through so far.
96	MR. DR. LIMBURG: Well, these are all things that are not only interesting for private patients. These are just as interesting for the AOK or the Techniker Krankenkasse (<i>Note: Two of the biggest public health insurance companies in Germany</i>) or whatever. I also consider the kind of activity that you are doing just for absolutely meaningful. Generally, bringing a structured improvement in health care is absolutely sensible.
97	VIKTOR: Yes, thank you, that encourages me in my endeavour.

6.5 Interview with Mr. Prof. Dr. Thomas Weiss

#	Interview
1	VIKTOR: Good day Thomas. Is it okay for you if I record this conversation?
2	MR. PROF. DR. WEISS: Yes
3	VIKTOR: So you're right with your rough assessment that it's (<i>Note: the interview</i>) intended primarily for doctors with direct patient contact, but still I would be interested in your opinion on the subject. That's why I do not know if all the questions are so perfectly fitted for your area, but let's just have a look.
4	MR. PROF. DR. WEISS: Well, I see patients, I just do not treat them. And I can see them if I want to see them. Otherwise, they will of course be x-rayed or examined without having any contact with me.
5	VIKTOR: Ok.
6	MR. PROF. DR. WEISS: Okay, let's start.
7	VIKTOR: So then my question would be to get started, just about your career. What do you do? Just like that.
8	MR. PROF. DR. WEISS: Yes, 1970 A-levels, then medical studies in Berlin. Then medical assistant in three hospitals specializing in surgery, internal medicine and gynaecology. Then beginning of the assistant in the hospital Westend, hospital Charlottenburg 1978. And there functional senior physician 1981 and there habilitation 1985. And attendance there 1978 to 1988 or 1987. Then admission of the occupation, the occupation in the practice as a radiologist with the method of magnetic resonance tomography and computed tomography with colleague Kostadinov in Berlin-Friedenau at Walther-Schreiber-Platz, which borders on Steglitz. Then Professor 1993. Associate Professor of Medicine and Biology. Then activity in practice there from 1988 to 2008. Parallel to this operation of an X-ray institute in Berlin Siemensstadt 1987 to 1999 and parallel overlapping orthopedic oriented MRI facility in the hospital Havelhöhe from 1999 until now. Exit from the practice in Friedenau 2008, exclusive activity from 2008 to 2016 in the nuclear spin tomographical facility at 247 Gatower street next to the hospital Havelhöhe.
9	VIKTOR: Ok, thanks in any case for the entry, there were now also a few things that I did not know yet. Sounds very exciting in any case. Um, then I would say, let's get to the first content-related topic block and there it goes: Which measures or tools you use to determine the success of a treatment?
10	MR. PROF. DR. WEISS: Yes, subjective criteria, well-being of the patient. Then objective criteria: medical examination by eye diagnosis, physical examination, laboratory medicine, blood collection, blood chemistry depending on the disease and possibly additional imaging procedures: X-ray ultrasound, computer tomography, magnetic resonance imaging, nuclear medicine.
11	VIKTOR: Ok, you've already touched an interesting point. And indeed, there is the following question: To what extent do you think it is necessary to ask patients directly for feedback in order to assess the success of the treatment?
12	MR. PROF. DR. WEISS: The attending physician is always in close contact with the patient

	and will then experience the success or failure of the patient. So, in contact between doctor and patient. Feedback is essential.
13	VIKTOR: And what would you say? How important is it to assess the health-related quality of life of patients?
14	MR. PROF. DR. WEISS: That's very different today. Since every patient takes different measures and rules and there are conventional medical recommendations from medical professionals, how to behave as a human, so that you can achieve a high life expectancy. And what toxins one avoids, in order not to suffer this condition. The behavioural measures, the recommendation for sports and nutrition are highly variable. Incidentally, not only within the German interior, but also European and worldwide. Totally different views and recommendations.
15	VIKTOR: Ok and have you already heard about measurements of health-related quality of life or quality of life measurements?
16	MR. PROF. DR. WEISS: I've read about it. I know that it exists, but I have no closer knowledge of it.
17	VIKTOR: Ok, because there is a bit of a drum around here now. I can just briefly read you the definition of it: In health care, health-related quality of life is a patient's assessment of how individual wellbeing over time is affected by illness, disability, or disorder. Health-related quality of life covers the status of psychological, physical, functional and social health.
18	MR. PROF. DR. WEISS: Ok. Very high standard.
19	VIKTOR: Ok, so you've heard of it a bit before, but ..
20	MR. PROF. DR. WEISS: Yes, I know that one always tries scientifically to objectify the condition of the human being in relation to his mental and physical, to his mental and physical functionality. This is always tried again.
21	VIKTOR: And do you happen to know any means of measuring the health-related quality of life?
22	MR. PROF. DR. WEISS: No, there are no general funds. There are a whole range of possibilities, I believe. Sports medicine, normal physical examination and it always has to cooperate with the patient. So the patient must also want to give the information and must then perhaps want to use the information for themselves and there are various approaches that you can operate. The typical approach is the examination in schools and medical screening in the military. You get large groups of people to judge and can classify them in terms of their physical integrity, but not on their mental function, not on their psychic life.
23	VIKTOR: Ok, so I suppose - from what I conclude from your answers - that in the organizations where you work or have worked, there were no health-related quality of life measurements performed there?
24	MR. PROF. DR. WEISS: No, we did not do any prospective studies on how people are doing, we acted on demand. We were presented with ill or supposedly ill people or those who thought they were ill or those the doctor thought were ill or could be ill. And we had to then clarify whether that is true from our perspective.
25	VIKTOR: Ok, what do you think would be an area, where you could need these measurements? Do you think of any areas?
26	MR. PROF. DR. WEISS: You are talking about prospective studies for the human condition now right?
27	VIKTOR: Yes, so the quality of life measurements that examine the psychological, physical, functional and social aspects of health - I say.
28	MR. PROF. DR. WEISS: So there are different groups interested in it, I believe that currently play a role in influencing society in general: So business groups and groups want to sell things. To put it mildly. It is certainly interesting for many. This plays an important role in the food industry and also generally in the research of customer behavior. That one tries to find out how, when a person feels comfortable and with what. With which material and literary and musical, artistic, but also normal things of everyday life. Or maybe very big with sports things nowadays and for nutritional reasons. This is very interesting for the industry. They want to know that and

	they are doing research.
29	VIKTOR: Ok, and what options are there to capture that?
30	MR. PROF. DR. WEISS: Through questioning and observation and by studying people's behaviours. And by watching their consumption behaviour.
31	VIKTOR: Ok. So, then the next question - which is probably already done - from your answers, I also understand that there are no efforts now in your organization to perform such quality of life measurements soon.
32	MR. PROF. DR. WEISS: No, so we radiologists do not have a topic open in this area at the moment. I do not know how far I read that. We have the Deutsches Ärzteblatt (<i>Note: Monthly magazine for doctors</i>), that is the organ of the German Medical Association. And that's what all the hospital doctors, clerks and general practitioners, that is, the doctors working in the practice, and even retired doctors get sent. Also, laboratory doctors and pathologists. And here we get big news about all medical claims in Germany, Austria and Switzerland. And there are always such studies mentioned and one tries again and again such approaches to undertake such viewing approaches and comes to no result.
33	VIKTOR: Ok, can you maybe explain a bit further? How can one not come to a result?
34	MR. PROF. DR. WEISS: Because the expectation in the area of the questioner is already pre-interpreted by bias, so that no good question comes to pass. So, the question is not so objectively posed that any respondent, who would have to have an intellectual level that would have to satisfy this question, could answer well and satisfactorily. So, often the questions are already so subjective and biased that the respondent gives the answer in the direction of the questioner's interest. So, it is certainly also very difficult to ask objective questions and it is also the different population groups that one has to take into account in their social status and their geographical distribution and in their age profile. And also in relation to man and woman, so gender distribution.
35	VIKTOR: Ok, so it's important to make sure that you ask questions that are as objective as possible and not something, that is...
36	MR. PROF. DR. WEISS: Yes, do not ask biased questions.
37	VIKTOR: And what do you think is relevant in the evaluation? Once you have collected this data, what do you think could play an important role in evaluating this data?
38	MR. PROF. DR. WEISS: I cannot think of anything now. So being as objective as possible regarding reconditioning is generally involved and what we have discussed the last few minutes. So usually the questioners are interested in having a result in terms of consumer behaviour, on health integrity, on education content of respondents again on consumer behaviour and maybe on food habits. And this is then evaluated separately by divisions. Not with this general big denominator that you are trying to formulate now. So, there is no Einsteinian world formula for the human and his sensitivities, but we are already sorted by categories in terms of eating habits, man and woman, old and young, the Americans would add civilian and soldier, geographical distribution and such things
39	VIKTOR: Okay, so I'll say: The application that I'm now familiar with - from such quality of life measurements - is to judge treatments as well. Or to be able to judge the success of treatments by comparing them: How is the patient with treatment A after 6 months, and how is the patient with treatment B after 6 months? And then you can just track it, if you measure this quality of life: "Ok, with the treatment A, the patients are much better off than with treatment B!". And then you can say, "OK, this treatment B will not be performed anymore because the quality of life was significantly higher for patients who have received treatment A in comparison to the other group of patients."
40	MR. PROF. DR. WEISS: Yes, now it becomes concrete. Since now I can give quite concrete answers. That's succeeded. This has been achieved in medicine and has progressed far, at least in Germany: Here we have the quality assurance standards. We have all the diseases that are sorted out and all the mental disorders. And the treatment for all these diseases are standardized according to special guidelines, some of which are determined by the associations of statutory health insurance physicians and health authorities. So, there is a strict set of rules, which of

	course also takes into account the success of all these methods and that might be applied only methods that - especially in the healing field, in the treatment area - are effective. Typical example: diabetes, hypertension, arrhythmia. And that is regulated. Up to regulation of the attending physician, to patronizing the behaviour of the attending physician, who sometimes wants to give the tablet A, but only gets tablet B recommended and only gets paid if he prescribes tablet B. This has been regulated in an exemplary way for about 15 years.
41	VIKTOR: Ok, and now there is the idea that one thinks to raise these quality of life measures not only punctually to look "how is treatment A against treatment B", but that it is properly established permanently in hospitals and practices, even to be able to compare hospitals against each other and to be able to say: "Ok the quality of life of the patients in hospital A develops much better than in hospital B" and that then patients can see so to speak "Oh hospital A is much better than hospital B, then I better go to Hospital A ".
42	MR. PROF. DR. WEISS: This is also regulated. For about 10 years, there are also rankings published in public newspapers: rankings of good and bad hospitals in quotes. And often these are surgical clinics, which are surgical and perform orthopedic-surgical and vascular surgery. Then one can measure the frequency of the performed operations in the year or in the unit of time how well the colleagues master this method. Sometimes the frequency increases the quality. This is assumed first. They have to announce their mistakes of course, but do so only with restrictions. And there are of course all human reservations involved, which allow an objective assessment. But this is tried and done and partly checked by the health insurance companies and checked by patient initiatives. And there are guidelines that of course take into account the differences in experience between the treating physicians among each other, which are then published in the relevant journals and regional magazines. There are certain hospitals mentioned which achieve great effectivity to which then patients are referred. For mostly well verifiable surgical procedures. Internal measures or treatments are harder to check because the results are often more diffuse, failing, or influenced differently by patient compliance. Yes, in conservative treatments that are non-surgical: tablet administration, observation, warm white hands, baths and so on, there are different reactions of patients that are difficult to assess, which also strongly depend on the individual type of the patient. From his soul and his willingness to cooperate, ability to cooperate. For surgical procedures, you can check that much better. Whether the operated blood vessel is continuous, whether the operated hip joint works, whether the herniated disc is gone. That can be checked.
43	VIKTOR: Ok, so that would be the question from the penultimate topic block. So I'll just read it out like this. Do you generally consider patient-reported outcomes to be beneficial in your daily practice?
44	MR. PROF. DR. WEISS: Absolutely. Must be included, but objectively reviewed. The patient says he is limping, but he does not limp if you let him try out.
45	VIKTOR: Ok, and in terms of this permanent measurement of quality of life. Do you think that would be useful in your daily practice? Do you think it would be beneficial for you to keep this information up-to-date?
46	MR. PROF. DR. WEISS: I do not know how this would be done organisationally on the part of the affected patients. Whether that should be surveys or physical examinations or equipment for medical examinations or blood withdrawals. How do you want to do that?
47	VIKTOR: Yes, that's mainly done with questionnaires.
48	MR. PROF. DR. WEISS: Can you try then. Yes, then you can try. But the patients will be different - depending on their mental ability and their intellectual level, they will give completely different answers.
49	VIKTOR: In your opinion, what would be the main reasons why this quality of life is not permanently recorded?
50	MR. PROF. DR. WEISS: The difficulty of the endeavour. The high benchmark. The impossibility of reaching this state, this result. Ok, you can always do it only with certain groups or with certain disease types, disease pictures do what is also tried and done, but you get no general standard of well-being for the entire population.

51	VIKTOR: Ok, so you see now no need for such measurements in your ...
52	MR. PROF. DR. WEISS: Honestly, no. But that's my personal opinion and maybe otherwise... You should strive for it, but we have talked about how difficult the instruments are to do it.
53	VIKTOR: And what kind of advantages could you imagine if it were to implement such measurements of quality of life?
54	MR. PROF. DR. WEISS: To inform the concerned person about his chances to continue his life healthy, painless and long. That one returns it to the interviewee.
55	VIKTOR: Ok, and we have already mentioned disadvantages: In the organizational area - what you have addressed. Could you perhaps give an example of a problem that you would have if you started doing those measurements now?
56	MR. PROF. DR. WEISS: The problem of organization, the problem of financing, the problem of the formulation of the test circle, the visual field, the scope of testing. What do you want to check? Well-being, good dreams, heartburn yes or no? Well-being, bowel movements, how often? Quite different in the people. Freedom from pain. Many also have imagined pains or others who do not feel pain. Ailments, age-related difficulties. Very young people have other problems: imbalance. Difficult to do that ... as you have said, you have to sort it by age, correct it by gender, correct it by geography, sort it by racial or nationality, by country team, by geographic and genetic positions and dispositions. Bavarian citizens respond differently to North Germans, Hessians differ from Thuringians, have different flavors, have different sports, different travel destinations. Difficult.
57	VIKTOR: Ok, which is also a field of application, what I have noticed is especially in oncology or in general in cancer patients, so as to be able to observe a bit the course of the disease and to be able to say "How is the patient in the course of treatment? Does the pain increase or decrease? Which complaints have been added or dropped? Such stories might still be positive. So that you really apply it to certain diseases in order to be able to recognize such a course better.
58	MR. PROF. DR. WEISS: Well, that's what you do. You mean that you should do all that, what you just mentioned to promote and support the investigation?
59	VIKTOR: Exactly. Because that might be neglected in everyday life.
60	MR. PROF. DR. WEISS: All I can say is that you can curb, limit or in some cases greatly reduce cancer through behaviors, certain stimulants, but you cannot change some types of cancer. Some can be virtually eliminated by preventive care, by regular provision. So, colon cancer and uterine cancer can be practically eliminated - and this happened – through precautionary measures. For breast cancer, you try that and it succeeds - I would say - on 60% of the cases. All other cancers are unpredictable.
61	VIKTOR: Ok, but let me just put it bluntly: If it is already too late, you can just look: "Ok, which symptoms have been added?"
62	MR. PROF. DR. WEISS: Yes, that's what you do. This is all conventional medicine and also otherwise under control. You will see that later, when you have advanced in your own education. That's very good and will be much better. By the way, standardized. In my youth, this was not standardized and at the time of your mother's youth. There were recommendations and everyone did as he wanted and every clinic did it differently. Today this is very standardized within Germany and sometimes even in Europe. And there are very clear guidelines and they are certainly based on good empirical values. Great progress.
63	VIKTOR: Ok, and how is that recorded? Also with questionnaires or in the doctor-patient conversation?
64	MR. PROF. DR. WEISS: Through clinical trials, scientific. At universities. You treat patients or examine patients in a certain way and document this and evaluate it from a scientific point of view. Hire PhD students who will then do it and if successful and, incidentally, even in the case of a negative success, get their doctorate and then it will be published. And then it has to be reproducible in different places in the country and worldwide to be valid. And then it is proven. If it can be done in Sydney as well as in Münster, then it was probably right. If it only succeeds in Münster, then it is wrong. Treatment and diagnostics.

65	VIKTOR: Ok, and I'll say that in everyday life. If there is a patient now. How is it determined if the symptoms have certainly improved or worsened? Simply by a doctor-patient conversation or is there something else?
66	MR. PROF. DR. WEISS: Yes, by conversation. Then inspection, i.e. consideration of the patient, examination of the patient with the hands or with stethoscope and other aids. And if that is not enough by ultrasound, because that is also very gentle and is cheap and fast. And if that's still not enough by imaging techniques, where I'm responsible again. X-ray, ultrasound - is also imaging, computed tomography, magnetic resonance imaging, nuclear medicine.
67	VIKTOR: Ok, but you can not imagine that such a questionnaire could be used as a criterion?
68	MR. PROF. DR. WEISS: Who should fill it out now? The patient?
69	VIKTOR: The patient, exactly.
70	MR. PROF. DR. WEISS: The patient is often unable to do this. So he cannot classify his own situation. You can try it and then you can sort the questionnaires, which are evaluable... you could triage them accordingly to how reasonable the patient filled it out - whether questions have been omitted. Test questions can be incorporated to find out whether the patient, the responder was engaged, whether he is intellectually capable to answer. And if such a questionnaire meets these requirements, one could execute it.
71	VIKTOR: Ok, then we are already at the last topic block with the last five questions. And then there is my question: So let's assume that one would actually introduce questionnaires in order to gain even more data. So it also has a bit related to the topic of digitization and data collection which is somehow currently on everyone's lips.
72	MR. PROF. DR. WEISS: Yes, you cannot get past it.
73	VIKTOR: And here's my question, what do you think would be necessary skills or resources to really capture that data?
74	MR. PROF. DR. WEISS: Well those are digitized. The flood of data is so big and so huge that you can only handle it digitally. Especially, since statistical analyses are necessary to relate to the reliability of the data collected and the whole evaluation and quantification. And qualification. That can only be done digitally.
75	VIKTOR: And do you have any incentive to acquire skills in this area or is this not just a debate for you at the moment?
76	MR. PROF. DR. WEISS: For reasons of age not up for debate. If I was younger, I would keep up and I try to keep up with my age with the digital possibilities and the digital information that is accessible to me.
77	VIKTOR: Ok, so I assume that you do not plan to train staff in this area?
78	MR. PROF. DR. WEISS: We already do. In our practice, we have employees, but not in this very big one you're aiming for. So, our employees are not swarming for training to explore the patient's overall global well-being level. That certainly not.