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Paying for Community Pharmacy-Based Medication Reviews for Type 2 Diabetes:

A Feasibility and Budget Impact Analysis

Master Thesis

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Abstract

Background: The medication treatment of type 2 diabetes often requires polypharmacy which is associated with an increased risk for adverse drug events. Medication reviews aim to identify drug-related problems and have been implemented in various countries as a reimbursed service provided by pharmacists. In Germany, recent political arbitrations have boosted the discussion regarding the reimbursement of pharmaceutical services and medication reviews, but as of today, no decision has been made. Accordingly, it is necessary to analyse the financial feasibility of reimbursing medication reviews for the statutory health insurance as the main budget holder.

Objective: To estimate the financial implications when reimbursing medication reviews for people with type 2 diabetes and to identify a feasible remuneration rate as well as requirements for the reimbursement of community-pharmacy based medication reviews.

Methodology: In a business impact analysis, the financial consequences of the reimbursement of medication reviews for people with type 2 diabetes have been illustrated for a five-year period to identify financially feasible scenarios and remuneration rates. In two expert interviews requirements for the reimbursement of medication reviews have been identified.

Results: The reimbursement of medication reviews can be feasible in some scenarios but depends on the set remuneration rate, size of the population and the chosen acceptance threshold. Identified requirements include documentation, educational training, use of digitalized tools, and knowledge databases. In the future, there is the need for evidence-based patient-related outcomes.

Conclusion: Medication reviews for people with type 2 diabetes can be financially feasible for statutory health insurance. There is the need for more clarity regarding the general conditions for providing pharmaceutical services in Germany and more research is needed to be able to analyse the cost-effectiveness of this intervention.

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Abbreviation

ADE	Adverse Drug Event
ApBetrO	Apothekenbetriebsordnung
BIA	Business Impact Analysis
BMG	Bundesministerium für Gesundheit
CEA	Cost Effectiveness Analysis
CDSS	Clinical Decision Support System
DAV	Deutscher Apothekenverband
DPhG	Deutsche Pharmazeutische Gesellschaft e.V.
DRP	Drug Related Problems
EHR	Electronic Health Record
EMA	European Medical Agency
GKV-SV	GKV-Spitzenverband
ISPOR	The Professional Society for Health Economics and Outcomes Research
MTS	Medication Therapy Safety
MRs	Medication Reviews
NVL T2D	Nationale VersorgungsLeitlinie Type 2 Diabetes
OTC	Over-the-Counter
PC	Pharmaceutical Care
PCNE	Pharmaceutical Care Network Europe
PIM	Potentially Inadequate Medication
QoL	Quality of Life
T2D	Type 2 Diabetes
SHI	Statutory Health Insurance
RKI	Robert Koch-Institut
VOASG	Vor-Ort-Apotheken-Stärkungsgesetz
WHO	World Health Organization
WTP	Willingness-to-Pay

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1 Introduction

With diabetes, the world is facing one of the greatest public health challenges of the 21st century characterized by increasing prevalence, significant economic importance, and need for cross-sectoral treatment (World Health Organization, 2016a).

Diabetes is a metabolic disease that occurs when the pancreas is not able to produce enough insulin or when the produced insulin cannot be used effectively, causing a constant high blood sugar level (World Health Organization, 2021).

It is estimated that 463 million people had diabetes in 2019. Furthermore, it is estimated that in the same year more than 4.2 million people died because of diabetes or its complications (International Diabetes Federation, 2019). Most people with diabetes, about 90%, are diagnosed with type 2 diabetes (T2D) which occurs when the body resists insulin. Unlike type 1 diabetes, which is rather diagnosed in people of younger age and assumed to be caused by an autoimmune reaction, T2D is more common in elderly and often preventable as its risk factors include unhealthy behaviours such as unhealthy diets or physical inactivity (International Diabetes Federation, 2019).

According to the Robert Koch-Institut (RKI), 9.2% of the people living in Germany have T2D with 2.0% attributing to an unknown diabetes (Robert Koch-Institut, 2019). A projection of the number of people with T2D estimates an increase between 54% and 77% from 2015 to 2040 (Tönnies et al., 2019).

In recent decades the demographic shift, urbanisation and obesogenic environments were contributing to the increasing prevalence of T2D (Napier et al., 2017). Especially demographic ageing is of great relevance as older people also tend to have multiple chronic conditions and are more likely to use various medications (Robert Koch-Institut, 2019). Polypharmacy, mostly defined as the use of at least five preparations (Masnoon et al., 2017), is considered as a higher risk for drug-related problems (DRP) often associated with medication non-adherence, hospitalisation or even death (World Health Organization, 2016b). It is estimated that 42% of elderly over 65 take at least five prescribed drugs. However, this estimation does not include over-the-counter (OTC) medications which leads to the

assumption that polypharmacy could be even more common (Moßhammer et al., 2016).

In the past years, pharmacies started to perform medication reviews (MRs) with the aim to improve the medication therapy safety (MTS) for people with polypharmacy. First international studies indicate some positive outcomes of MRs (Al-Babtain et al., 2021a). MRs are not part of the patients benefits catalogue and therefore not reimbursed by the SHI in Germany (Imfeld-Isenegger et al., 2020).

Nonetheless, the discussion regarding a possible remuneration of MRs is more current than ever. With the implementation of the Vor-Ort-Apotheken-Stärkungsgesetz (VOASG, **in English:** German On-Site Pharmacy Strengthening Act) the Bundesministerium für Gesundheit (BMG, **in English:** Federal Health Ministry of Germany) aimed to strengthen the role of pharmacies and provide them with more competencies to perform reimbursed pharmaceutical services (Deutsches Apotheker Portal, 2021). However, the institutions in charge of the exact implementation – Deutscher Apothekenverband (DAV, **in English:** German Pharmacy Association) and GKV-Spitzenverband (GKV- SV, **in English**: National Association of Statutory Health Insurance Funds) - were not able to decide on the scope and remuneration of pharmaceutical services and it is not sure when the two parties are going to find an agreement (Sucker-Sket, 2021).

Some pharmacies perform MRs which are reimbursed out-of-pocket or within selective contracts, but the lack of remuneration by a budget holder is often considered as one of the main barriers towards the implementation of MRs in pharmacies (Michel et al., 2021).

Therefore, this thesis aims to examine the financial feasibility of reimbursing MRs for people with T2D. For this, a business impact analysis (BIA) was conducted, and the financial implications were analysed by testing scenarios with different utilisation and remuneration rates. With the help of two interviews with experts from the SHI, the requirements for the remuneration of MRs were identified.

This elaboration answers the following research questions:

1. What are the financial implications of reimbursing medication reviews for people with type 2 diabetes for the statutory health insurance?

2. What requirements should be fulfilled in pharmacies to be able to reimburse medication reviews?

2 Objectives

The main objective of this paper is to examine the financial feasibility of the reimbursement of MRs as performed at the community pharmacy level by analyzing the financial implications for the SHI.

Based on the BIA, various scenarios will be tested with the aim to identify the minimum of total expenditures when implementing MRs for people with T2D in Germany.

It is aimed to identify the maximal feasible remuneration rate and to discuss its implementation under consideration of the political debate. In addition, the identified remuneration rate will be compared with remuneration rates in other countries.

Based on the expert interviews, requirements for the remuneration of MRs will be discussed and recommended. Furthermore, general prerequisites for the implementation of MRs will be identified.

3 Background

This chapter gives a short background on the topics relevant to the research topic and for answering the research questions.

MTS is described by explaining the importance for patients and the ambitions towards its improvement. In this context, the definition for the terms *medication review* and *medication management* is given.

The role of the pharmacy is portrayed by highlighting the economic relevance and the purpose of the pharmacist in the health system in Germany. Here, a short background of the current reimbursement of pharmacies is given.

The third part of this section describes the economic and medical relevance of T2D. It concludes with an appraisal on the eligibility to (possibly) benefit from MRs by providing a short literature review.

3.1 Definition of Medication Therapy Safety

Medications (synonym: drugs) aim to alleviate or cure ailments and are an essential component in drug therapy and the medical field. Although medications have the purpose to brings benefits to patients, adverse drug reactions (ADR) may occur. Commonly known as side-effects, ADR can cause mild symptoms like headache or upset stomach but can also lead to more life threatening reactions causing hospitalisation, disability or even death (Center for Drug Evaluation and Research, 2021). ADR are characterised as reactions caused by a medication under appropriate use (i.e. at normal doses) and as a subset of the so-called adverse drug events (ADE) (Nebeker et al., 2004).

Other than ADR, ADE can be caused by both the appropriate and inappropriate use of medications, for example, through medication errors and non-adherence (Nebeker et al., 2004). ADE are common and considered as a recurrent reason for hospital admission as indicated from the results of a systematic review in 2011 (Taché et al., 2011). There, the median ADE prevalence rate was 3.3% (retrospective studies) vs. 9.7% (prospective studies), the median preventable rate for ADE in ambulatory care-based studies was 16.5% and in hospital-based studies 52.9%.

Medication errors are considered as a main reason for preventable ADE but are also considered as facilitating outcomes such as lack of medication efficacy, suboptimal therapy adherence or poor quality of life (QoL) and patient experience (World Health Organization, 2016b).

The European Medical Agency (EMA) defines a medication error as "*an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient*" (EMA, 2018). Per definition, a medication error can be committed at any step of the medication process (Figure 1) by the patient, the doctor, the pharmacist, or any other actor (EMA, 2018). It is important to comprehend that a medication error does not need to lead to harm; it is sufficient that the medication was administered incorrectly.

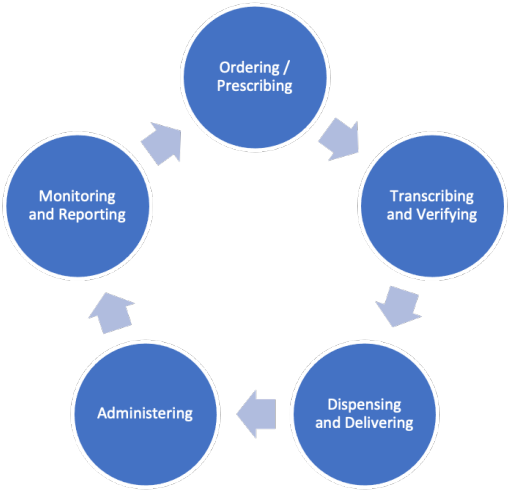

Figure 1 Steps of the Medication Process

With the acknowledgement of medication errors, especially through the publication of "*To err is human*" by the Institute of Medicine (US) Committee on Quality of Health Care in America in 2000, various strategies to prevent medication errors have been implemented in healthcare institutions globally.

One strategy to reduce medication errors and to avoid risks for patients during their drug therapy is MTS. MTS is the entirety of measures applied to ensure an optimal medication process (Aly, 2015). The BMG launched multiple action plans to support measures aiming to improve MTS in Germany since 2008. Currently, the action plan 2021 - 2024 aims to strengthen the health literacy of patients, the patient orientation, the collaboration between professions but also the use of digitalised possibilities (Bundesministerium für Gesundheit, 2021a).

However, one of the main accomplishments in MTS and with a relevant impact on the role of the pharmacy has been found during the time of the second action plan (2010 – 2012) with the revision of the Apothekenbetriebsordnung (ApBetrO, **in English**: Pharmacy Operations Ordinance) in 2012 (Bundesministerium für Gesundheit, 2016a).

The ApBetrO modernised the scope of pharmacy services and required pharmacists to actively contribute to MTS by providing information and advice to patients and physicians during the process of dispensing medications (section 20 ApBetrO).

3.1.1 Advancement of Pharmaceutical Care

Unlike the information and advice described in section 20 ApBetrO, medication reviews and medication management are two separate services not included in section 20 ApBetrO, which nevertheless also aim to improve MTS. Medication reviews have not been included in the ApBetrO, but medication management has been added to the catalogue of pharmaceutical services and can be found under section 1a subsection 3 ApBetrO.

Medication reviews and medication management are instruments of pharmaceutical care (PC) which has first been defined by Hepler and Strand as "*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve patient's quality of life"* (Hepler and Strand, 1990).

After the introduction of this new perspective on pharmacists, countries started to change the scope of the role of the pharmacist which led eventually to the establishment of the new pharmaceutical standard in the "Handbook on Patient Care" by the World Health Organization (WHO) and the International Pharmaceutical Federation (Richling & Rose, 2017).

In 2013, the Pharmaceutical Care Network Europe (PCNE) declared that "*pharmaceutical care is the pharmacist's contribution to the care of individuals in order to optimise medicines use and improve health outcomes*." (Allemann et al., 2014) and with that highlighted the importance of the pharmacist in the medication therapy and not solely during the dispensing of medications (Hersberger et al., 2013).

3.1.2 Definition of Medication Review and Medication Management

The origin of the term medication management is the American term *Medication Therapy Management* which has been defined by the American Pharmacists Association (Bluml, 2005). The first effort to develop a German definition for medication management has been made as an answer to the revision of the ApBetrO by the Deutsche Pharmazeutische Gesellschaft e.V. (DPhG, **in English:** German Pharmaceutical Association) in 2013 (Rose et al., 2013).

Based on the recommendations of the PCNE, medication management has been distinguished into three stages namely simple medication management,

intermediate medication management, and clinical medication management (Rose et al., 2013). However, shortly after the introduction of this definition, the ABDA – Bundevereinigung Deutscher Apothekerverbände e.V. (ABDA, **in English:** Federal Association of German Pharmacists) has adopted this definition for the term MR leading to a distinction of the terms *medication management* and *medication review* (Richling & Rose, 2017).

As of 2014, the following definition applies for the term *medication review* as defined in the policy paper of the ABDA:

> *A structured analysis of a patient's current overall medication of a patient. It comprises the four main steps: Identifying data sources and compiling the information, evaluating, and documenting manifest and potential medication-related problems, developing possible solutions, and agreeing on measures with the patient and, if necessary, with the attending physician(s). The goals are to increase the effectiveness of medication therapy and the minimization of drug risks.*

And the following definition applies for the term *medication management*:

> *Medication management is based on a medication review, which is followed by continuous care of the patient by a multidisciplinary team. With continuous care, agreed actions on detected drug-related problems and their outcome are followed up and adjusted if necessary. Emerging, manifest, and potential drug-related problems are identified, resolved, or avoided. Goals are to increase the effectiveness of drug therapy continuously and sustainably and to minimize drug risks continuously and sustainably.*
> (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014)

Accordingly, medication management and MRs are two separate approaches. A MR is the basis for medication management while medication management goes beyond a review and focuses on the continuous care of the patient by an interdisciplinary team. MRs do not necessarily have to be provided as part of a medication management program; they can also be provided as a stand-alone service.

Furthermore, the ABDA differentiates between different stages of MRs which are suitable for different settings depending on the availability of information (Table 1). However, all stages aim to improve MTS and therapy quality. Depending on the performed MR, different DRP can be identified (Table 2).

	Pharmacy Record	Brown Bag	Pat ent Informat on	C n ca Data (aboratory / d agnos s)
Type 1 (S mp e MR)	Yes	No	No	No
Type 2a (Intermed ate MR)	Yes or No	Usefu Yes	Yes Yes	No No
Type 2b (Intermed ate MR)	Yes	No	No	Yes
Type 3 (Advanced MR)	Yes	Usefu	Yes	Yes

Table 1 Classification of Medication Reviews according to (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V. 2014)

Type 1 medication review - also known as simple medication review - includes the patient's medication history as stored in the pharmacy report and basic information such as age and gender. A prerequisite for Type 1 MR is good data quality, but this is not always the case in public pharmacies. Nonetheless, the pharmacy can check for discrepancies of information if medication data are available from different sources. The pharmacy can perform a systematic check for interactions, (pseudo) duplicate medications, and contraindications. Since there is no knowledge regarding the patient's illnesses and not necessarily always about dosages, the type 1 medication analysis can only identify a small number of ADPs (Table 2) (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014).

The intermediate MR is divided into Type 2a and Type 2b medication reviews. In a Type 2a MR, data from a structured patient interview are available in addition to the pharmacy record. Frequently, a brown bag review happens here where the patient presents all the prescribed and OTC medications to get an overall overview of the medication taken. In addition to the ADPs identified in a Type 1 MR, other ADPs may also be found (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014).

A Type 2b MR includes data from the medical record or lab data instead of data from a patient interview. Here, extensive clinical data can be used to investigate whether there is an appropriate drug therapy for each indication and an indication for each drug. This information grants an accurate review of medication therapy in terms of safety and appropriateness for the patient (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014).

Type 3 medication review – also known as advanced medication review - allows the pharmacist to evaluate the medication therapy based on the medication history, patient interviews, and medical lab data. This form of MR is particularly time consuming but identifies all identifiable ADPs (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014). It differs from the original definition of medication management as it is not called “clinical” MR (Richling & Rose, 2017).

Adverse Drug Events	Type 1	Type 2a	Type 2b	Type 3
Interact ons	X	X	X	X
(Pseudo) doub e med cat on	X	X	X	X
Dosage nterva	X	X	X	X
Med cat on ntake	X	X	X	X
Contra nd cat on because of age or gender	X	X	X	X
App cat on ssues		X		X
Adherence ssuses		X		X
Dosage form		X		X
Adverse drug react ons (s de effects)		X		X
Med cat on se ect on			X	X
Dosage			X	X
Med cat on w thout nd cat on			X	X
Ind cat on w thout med cat on			X	X
Contra nd cat on because of a erg es or d seases			X	X
Unsu tab e or nappropr ate durat on of med cat on therapy			X	X

Table 2 Possible identifications of ADE by Medication Review Type according to (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V. 2014)

3.1.3 Medication Adherence and Health Literacy

As summarised MRs aim to identify DRP and solve them. But MRs can also be educational interventions that aim to support the knowledge regarding medications and the importance of medication therapy adherence (Blenkinsopp et al., 2012).

Therapy adherence is defined as "*the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider*" (Sabaté & World Health Organization, 2003). The lack of adherence is considered as one of the main barriers to the effectiveness of therapies (Sabaté & World Health Organization, 2003).

One reason for an insufficient therapy adherence is a low health literacy. The European Health Literacy Consortium developed the following definition for health literacy:

> *Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course* (Kickbusch et al., 2013, p. 4).

Limited health literacy is very common, it affects health and follows a social gradient which promotes further inequalities in health (Kickbusch et al., 2013). Misunderstandings of medication instructions or wrong applications of the medications happen more often in patients with limited health literacy which is in return associated with increased healthcare costs and worse health outcomes (Bazaldua et al., 2017).

With the pharmaceutical service of MRs, pharmacists can improve the health literacy of patients and therefore the therapy adherence by explaining the usage of medications in detail and the need for the specific medications.

Therefore, the implementation of MRs could not only be useful in terms of identification of unnecessary or contraindicated medications but also when trying to improve therapy adherence and health literacy.

3.1.4 International Terminology of Medication Review

As described, the terms medication review and medication management are not synonymous as they describe different services in Germany. As countries derived their definitions from the definition of PC, a distinction is not always given and, in some cases, the German interventions of medication review and medication management blur into one term (Richling & Rose, 2017).

Consequently, there is no standardised, international definition which leads to multiple services with various aims depending on the country and the applicable regulations (Bulajeva et al., 2014). This leads to the need to evaluate results of studies carefully as inconsistencies could be caused by different contents of MRs. In addition, evidence for effectiveness, expenditures or other outcomes of interest cannot simply be applied from one country to another. To provide a short overview of the international terminology, the concepts found in some countries are described in the following.

The United Kingdom was one of the first countries implementing MRs as a service in primary outpatient care. From 2020, all primary care networks are required to identify patients who might benefit from the so-called *Structured Medication Review* (NHS England, n.d.). Another term that was used in the United Kingdom before decommission in March 2021, was *Medicines Use Review* whose main goal was to improve the adherence by increasing the patient's knowledge of their medication (PSNC, n.d.). The Medicines Use Review was not a full MR but rather a short check of the medication and was reimbursed with £ 28 (PSNC, n.d.).

The American College of Clinical Pharmacy uses the terms "comprehensive medication management" for the MR and "collaborative drug therapy management" for the intersectoral collaboration (Richling & Rose, 2017).

The Australian guidelines use the terms *Home Medicines Review* or *MedsCheck*. Unlike in Germany, the pharmacist performs the review in the patient's home (Australian Association of Consultant Pharmacy, 2022).

In Canada, medication review programs have been widely implemented and are provincially funded with the remuneration rate ranging between $ 52.50 - $ 150 per MR (€ 37 – € 107 in Germany) (Pammett & Jorgenson, 2014). Although all MRs performed in Canada aim to provide education regarding the medications

and to identify and address DRP, the details and terminology differ, which causes inconsistency in the eligibility criteria and difficulties when comparing patient outcomes (Pammett & Jorgenson, 2014).

3.2 The Role of Pharmacies in Germany

From a health economic perspective, the supply of medications is an essential component of the healthcare system. In 2020, the turnover of the 18 753 German pharmacies (Statista, 2021) amounted to approximately € 61.4 billion – of which € 54.6 billion were prescribed medications (Bundesverband der Arzneimittel-Hersteller e.V., 2021). In the same year, roughly 1.5 billion medication packages have been dispensed. A total of 696 million were assigned to people insured in the SHI and 194 million to people insured in the private insurance scheme. The rest were dispensed as OTC medications (Bundesverband der Arzneimittel-Hersteller e.V., 2021).

The expenditure for medication supply is the third largest expenditure item after hospital treatment and outpatient treatment implying costs of roughly € 43.27 billion in 2020 (Bundesministerium für Gesundheit, 2021b). In the last decades, expenditure has steadily inclined, leading to an increase of 27.3% from 2010 to 2019 (Kassenärztliche Bundesvereinigung, 2022). Due to the increasing life expectancy and prevalence of chronic conditions, it is expected that expenditure for medications supply will increase in the future (Weingärtner, 2017).

Generally, community-pharmacies are being compensated based on constant fees and supply-prices for prescribed medications causing approximately 80% of the total revenue. Furthermore, pharmacies receive additional € 0.21 in a fund to financially support night and emergency pharmacy services. In addition, they are able to sell OTC medications which are usually not reimbursed by the SHI (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2021a). In many countries, including the United Kingdom, the United States of America, and Australia, pharmaceutical services, such as MRs, are being reimbursed. This is currently not the case in Germany, as they are separate interventions and not part of medication dispensing.

With the change to a more patient-oriented approach, the VOASG has been introduced in 2020. The aim of VOASG is to improve pharmaceutical healthcare by, for example, enabling pharmacists to offer pharmaceutical services in their pharmacies which are financially backed. The introduction of this regulation led to a revision of section 129 Sozialgesetzbuch V (SGBV, **in English**: German Social Code V) and entitled people insured in the SHI to receive pharmaceutical services that go beyond the duty of section 20 ApoBetrO (DAP Networks GmbH, 2021).

To financially support these pharmaceutical services, which, however, have not been specifically defined, the BMG planned to make available a budget of annually €150 million (Bundesministerium für Gesundheit, 2020). After a discussion between DAV and GKV-SV, they agreed that this budget is being financed by increasing the pharmacist's fee with additional € 0.20 per dispensed package (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2021b). Nevertheless, as of February 2022, there is still no clarification on how this additional remuneration is allocated to the respective pharmaceutical services and what pharmaceutical services are being included (Deutsches Apotheker Portal, 2021).

3.2.1 Medication Review in Germany

Although not known, it is assumed that MRs are going to be reimbursed within the framework of the VOASG. However, the general conditions for the reimbursement are not known, including for example the remuneration rate.

In Germany, some pharmacies already offer MRs where patients pay this service out of pocket. The ABDA advises a fee of € 60 (Richling & Rose, 2017). In pharmacies belonging to the ATHINA-network, the fee for MRs is € 69 (Landesapothekerkammer Baden-Württemberg, 2021) however, the fee may be different in other pharmacies or projects.

Two widely recognised projects in Germany are ATHINA and APO-AMTS. ATHINA (**A**rzneimittel **Th**erapiesicherheit **i**n **A**potheken) is a training for pharmacists where they learn to conduct 2a MRs in community-pharmacies. It was first initiated by the Kassenärztliche Vereinigungen (KV, **in English:** National Association of Statutory Health Insurance Physicians) NordRhein and is implemented by eleven

pharmaceutical associations now. In addition to the training of pharmacists, various studies have been undertaken to measure the outcome of MRs. A prospective study conducted within the ATHINA project concluded that MRs may improve medication and patient-related outcomes, however a causality could not be established (Seidling et al., 2021). In a different study from the University of Heidelberg, documentation sheets of MRs performed between 2012 and 2015 were analysed and the results suggest that community-pharmacists can deliberately identify patients with the need for information and with DRPs. Further, it showed that community-pharmacists were often able to solve problems with a MR (Seidling et al., 2017).

APO-AMTS, which was initiated by the pharmaceutical association of Westfalen-Lippe in 2012, also provides training for pharmacists. In a study, where 500 MRs have been performed by APO-AMTS certified pharmacists, medication plans were evaluated, and discrepancies identified. In 93.5 % of all cases, discrepancies were identified which led to the conclusion that MRs may have an important position in MTS as MRs provided the possibility to identify discrepancies in medication plans (Waltering et al., 2015).

In March 2022, it was announced that ATHINA and Apo-AMTS consolidated and unified their curricula. The two projects are found under the term “ATHINA-Verbund” now (Deutsche Apotheker Zeitung, 2022).

One of the largest projects is ARMIN (**Ar**znei**m**ittel**in**itiative Sachsen-Thüringen) which was initiated by KV Saxony, KV Thuringia and the SHI fund AOK PLUS in 2014. The aim of this project is to increase the quality of the medication-supply by improving MTS and therapy adherence through a close collaboration between physicians and pharmacists in the form of medication management (KV Sachsen, 2022). The starting intervention of the medication management approach in this project, is a MR which is remunerated with € 94.50 as of July 2015 whereby a yearly inflation compensation is targeted (Richling & Rose, 2017).

3.2.2 Barriers to Implementation of Medication Reviews

Although there are some examples of projects and initiatives where MRs are being performed, they are not offered nationwide. As one of the main barriers to implementation of MRs, the lack of reimbursement has been identified (Michel et al., 2021).

However, the lack of reimbursement is not the only challenge for pharmacists to implement this service. A systematic review which aimed to identify barriers to implementation of MRs in community-pharmacies showed that the professional collaboration between pharmacists and physicians can be a challenge (Michel et al., 2021). Although Type 1 or Type 2 MRs can be conducted without necessarily cooperating with a physician, this is not advised as the pharmacist is not allowed to change the prescription since this is solely the responsibility of physicians (Richling & Rose, 2017). Therefore, it is deemed crucial to collaborate with physicians to successfully provide solutions for problems with the medication therapy as identified by conducting MRs. When considering the importance of professional collaboration as mentioned in the definition of medication management and the fact that MRs are the foundation of medication management, the relevance of solving this barrier gets even clearer.

Further, MRs are a relatively new pharmaceutical intervention and as such not necessarily part of education at universities. Because of this, many pharmacists would feel insecure as they are unsure of how to conduct MRs of what is expected of them. This low self-efficacy has been described as a barrier for the implementation of MRs (Michel et al., 2021).

In addition, pharmacies need to meet requirements like an additional room for patient interviews or for the review of the brown-bag and, if possible, pharmacies should have access to electronic knowledge databases (Richling & Rose, 2017) or digital tools which could help performing MRs. For example, it is recommended (but not necessary) to use clinical decision support systems (CDSS), as they increase the standardisation of MRs and ensure quality standards (Haefeli and Seidling, 2018). However, because of the lack of remuneration, fulfilling these requirements is sometimes financially not bearable (Michel et al., 2021).

3.3 Comorbidities and Complications of Type 2 Diabetes

People with T2D could be beneficiaries of MRs, as they often have multiple morbidities and complications which reduce the QoL, increase mortality and morbidity, and cause additional health economic costs (International Diabetes Federation, 2019). The relative risk to experience complications or comorbidities as a person with diabetes is at least twice as high for stroke, twenty-two times higher for the amputation of lower excrements and five times higher to become blind (Icks & Robert Koch-Institut, 2005). As multiple morbidities are often treated with various medications, people with T2D often have polypharmacy.

Significant comorbidities of diabetes include obesity, hypertension, and cardiovascular diseases. The comorbidities are not only favoured by diabetes but also share many modifiable risk factors like physical inactivity or unhealthy diet (Robert Koch-Institut, 2019).

Diabetes can have an impact on small and larger blood vessels. At the microvascular level - that is, affecting the small blood vessels - organs such as the eye, kidney or nervous system can be damaged by diabetes and long-term elevated blood glucose levels. This can lead to complications such as diabetic feet, amputations, retinopathy, blindness, nephropathy, and kidney failure (Robert Koch-Institut, 2013).

At the macrovascular level - that is, part of the body's vasculature that includes the larger vessels - the most common complications are cardiovascular diseases such as myocardial infarction, stroke, angina and chronic heart failure (Robert Koch-Institut, 2013). Cardiovascular diseases are the leading cause of death in Germany and just like diabetes cause for great societal medical costs (Robert Koch-Institut, 2013).

3.3.1 Costs of Type 2 Diabetes

Diabetes and its complications and comorbidities are cause for a significant economic burden - both directly and indirectly. Direct costs are all costs occurring for the medical treatment of diseases; indirect costs include other economic consequences for example productivity losses because of morbidity or mortality.

In 2019, roughly 10% of the global health expenditure has been spent on diabetes (International Diabetes Federation, 2019). In Germany, it is assumed that diabetes related health expenditure amounts to € 37 billion (Montalbo et al., 2020).

In the analysis of a 6.8% random sample of routine SHI data collected in 2009 and 2010, the German Institute of Medical Documentation and Information (DIMDI) estimated that € 16.1 billion are spent on T2D with 39% attributed to hospitalisation costs and 25% to pharmaceutical supply. The same analysis also showed that the health expenses for medication-supply were 2.2-fold and for hospitalisation 1.8-fold higher for T2D than for people without diabetes (Jacobs et al., 2017).

A scoping review summarised that in 4 out of 5 cost-illness-studies the costs for the treatment of T2D are between € 3 350 and € 5 080. Further, roughly half of the costs were attributed to hospitalisation, 1/3 to the pharmaceutical supply and around 18% to outpatient-treatment (Müller & Stock, 2019).

Further, a study estimated that the annual indirect costs of T2D are 2.07 times higher for people with T2D than for those without (€ 4 103 vs. € 1 981) (Ulrich et al., 2016).

The main contributors associated with increased direct costs of T2D were found to be cardiovascular complications, a long diabetes duration and treatment with insulin (Ulrich et al., 2016). In a systematic review of 24 interventional, observational, and modelling studies on expenditures for T2D management in France or Germany, the researchers found out that the prevention of complications and glycaemic control are commonly acknowledged as the most effective ways to control diabetes treatment costs (Stegbauer et al., 2020).

In an analysis of SHI data of people with T2D, the costs of comorbidities and complications for a 60- to 69- year-old man has been calculated and illustrated (Figure 2). This has been one of the first estimations of costs for comorbidities and complications of diabetes based on SHI data and made it possible to see costs of various complications for the quarter of diagnosis, less than one year after diagnosis and more than year after diagnosis.

The estimation revealed that kidney failure costs roughly € 22 500 in the quarter of diagnosis and more than € 5 000 in the following years. A non-fatal stroke would

lead to costs of around € 9 500 in the quarter of diagnosis and up to € 1 500 in the following quarters (Kähm et al., 2018).

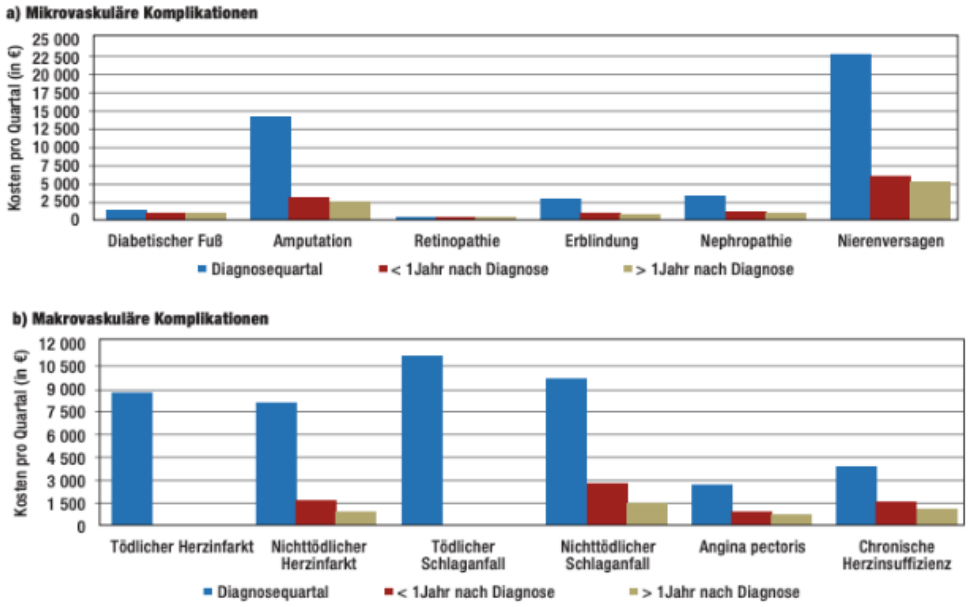

Figure 2 Costs for complications of diabetes (Kähm et al. 2018)

3.3.2 Treatment of Type 2 Diabetes

As described, the main drivers to control diabetes treatment costs have been found to be glycaemic control and prevention of complications and comorbidities.

It seems no surprise that the treatment aim is usually to lower and stabilise the blood glucose level and to prevent complications and comorbidities (Robert Koch-Institut, 2019). However, there might other or additional treatment goals and because of that and to improve the therapy adherence, the Nationale VersorgungsLeitlinie Typ 2 Diabetes Diabetes (NVL T2D, **in English:** National Type 2 Diabetes Treatment Guideline) stresses that the therapy goals have to be developed in a participatory approach with the patient and the patients' treatment team (Bundesärztekammer et al., 2021).

As described in the NVL T2D, it is generally advised to start with a non-medication therapy (basic therapy) which could include weight management, nutrition therapy or structured exercise programs. If not already in place, lifestyle changes consisting of a healthy diet and active exercise are often targeted. If the basic therapy is not

successful in reaching the treatment goals, a medication therapy consisting of oral antidiabetics or insulin is required. In addition, it is recommended to regularly monitor the therapy strategy and achievement of therapy goals as some medications have an impact on, for example, cardiovascular or renal endpoints. Thus, an evaluation and possible adjustment should take place in regular intervals of 3 to 6 months (Bundesärztekammer et al., 2021).

The medication therapy of T2D begins often with metformin. Metformin belongs to the biguanide class of drugs and lowers blood glucose levels in a variety of ways, including by inhibiting hepatic glucose production, delaying intestinal glucose absorption, and improving insulin sensitivity in liver and peripheral tissues. Based on the NVL T2D, metformin should be administered as monotherapy unless a high risk for diabetes-associated cardiovascular and/or renal events is given. If a high risk exists, for example, due to a clinically relevant renal disease, either monotherapy with metformin is started or combination therapy of metformin and a SGLT2 inhibitor or GLP-1-RS. Combination therapy is always pursued, if a clinically relevant cardiovascular disease is present. Additionally, the NVL T2D suggests that insulin injections may be necessary to reduce blood glucose when other medication-therapies do not achieve the targeted results (Bundesärztekammer et al., 2021).

Patients often aim to avoid insulin therapy as they fear a negative impact on QoL and reactions to the treatment (Kruger et al., 2015). For instance, insulin is a strong risk factor for hypoglycaemia (especially at the beginning of insulin therapy) and weight gain (Bundesärztekammer et al., 2021).

Hypoglycaemia is of a relevant concern and should be avoided. Hypoglycaemia is the medical term for the state of a low blood sugar level. It is characterised by a low concentration of glucoses in the blood – often considered as lower than 45 mg/dl – and depending on the severity, cause for symptoms like nausea, tachycardia, aphasia and neurological problems like seizures, unconsciousness, and coma. In addition, long-term hypoglycaemia can lead to sudden unconsciousness, known as hypoglycaemic shock and is often associated with hospitalisation (Grosser et al., 2021). Consequently, hypoglycaemia can lead to high costs (Quilliam et al., 2011) and a loss of QoL (Jódar-Gimeno et al., 2015).

3.4 Medication Review for Type 2 Diabetes

The multimorbidity of diabetes requires interdisciplinary care. However, interdisciplinary care across multiple medical professions comes with risks like cascades of prescriptions or prescriptions that are incompatible with each other (Kalisch et al., 2011). Problems in the medication therapy remain hidden, as maybe a lack in the communication between physicians (Kalisch et al., 2011) or an insufficient health literacy in especially older patients exist (Parekh et al., 2018).

At the same time, the prevalence of T2D is higher in the elderly population (Robert Koch-Institut, 2019). For this population, there are additional lists, like PRISCUS, where potentially inadequate medications (PIM) and additional suggestions for treatment alternatives are being summarised and described (Private Universität Witten/Herdecke gGmbH, 2022). As physicians are sometimes unaware and unintentionally prescribe PIM, this list aims to provide more information and is being frequently used in MRs performed by pharmacists (ABDA-Bundesvereinigung Deutscher Apothekerverbände e. V., 2014).

With age, the ability to take the medications as necessary and prescribed may decline. With a reduction in cognitive abilities, individuals may forget to take their medications or may not recognize them as medications as this is often the case for people with dementia. In addition, physical limitations can cause application issues and add to problems with the therapy adherence (Yap et al., 2016).

Further, certain medications used in the treatment of T2D increase the risk for serious side-effects and complications. Examples are the contribution of medications to an increased risk of frailty - which should be avoided at all costs in frailty-prone individuals or the impact of medication on the liver or kidney which could lead to liver or kidney failure in the worst case scenario (Bundesärztekammer et al., 2021).

Unfortunately, the literature is inconclusive regarding the benefits of MRs performed in this group and RCTs are rare. A systematic review of RCTs showed that MRs could significantly reduce both HbA1c and blood pressure in patients with diabetes (Al-Babtain et al., 2021b). In a different systematic review of thirty-one RCT studies, no effect was able to be established for hospitalisation admissions, mortality or QoL (Huiskes et al., 2017). It must be stressed though that this systematic review did not

focus on people with T2D; however, there are no publications suggesting that this outcome might be different for this target group.

The impact of MRs performed in German community-pharmacies under real-life conditions has been evaluated in the DIATHEM study (Schindler et al., 2020). The results of the MRs showed that 4.84 DRPs per patient were identified of which 31.6% were related to antidiabetics. After the performance of MRs, a statistically significant decline from 4.84 DRPS to 2.57 DRPs per patient ($p < 0.001$) has been noticed. Additionally, the average number of drugs was significantly reduced which led to the conclusion that MRs in elderly patients with T2D can successfully be performed under routine care in community pharmacies (Schindler et al., 2020).

In a qualitative study from 2014, thirty-one patients with polypharmacy, at least three chronic conditions and older than 60 years were asked to provide information about their attitudes towards MRs to identify patient-perceived barriers and facilitators to the implementation of MRs. The researchers concluded that patients perceive MRs as beneficial and anticipate that indications for their medicines are checked, and DRP identified (Uhl et al., 2018).

Because of the risks and side-effects, the importance of therapy adherence to prevent complications and comorbidities, and the significant costs of diabetes and its complications, it is necessary to optimise the medication therapy and the MTS for people with T2D. As people with T2D often use antidiabetic medication, they can be identified by community-pharmacists which provides a starting point for the performance of MRs for this patient group (Schindler et al., 2020).

4 Methods

To answer the research questions, it was decided to develop a business impact analysis (BIA) and to conduct additional interviews with experts from the SHI. In the following, first the methodology of the BIA is being described and afterwards the methodology of the expert interviews.

4.1 Preliminary Consideration

Currently, there is no conclusive evidence on decisive benefits by providing MRs to patients. Nonetheless, many assumptions regarding possible outcomes of MRs have been found in publications and already mentioned in the background.

Both for the development of the BIA and the development of questions for the expert interview, it is necessary to know the *possible* impact discussed in the literature. To provide a short overview on what impact MR may have on what resource or outcome, a very simple conceptual model has been developed which simplifies and illustrates the presumed impact (Figure 3).

In the future, it is necessary to address the cost-effectiveness of MRs as this is a main part of a comprehensive health economic model. In this study, a cost-effectiveness-analysis (CEA) has not been performed as the lack of conclusive evidence does not provide the opportunity and it would not add value to the current research because of the uncertainty.

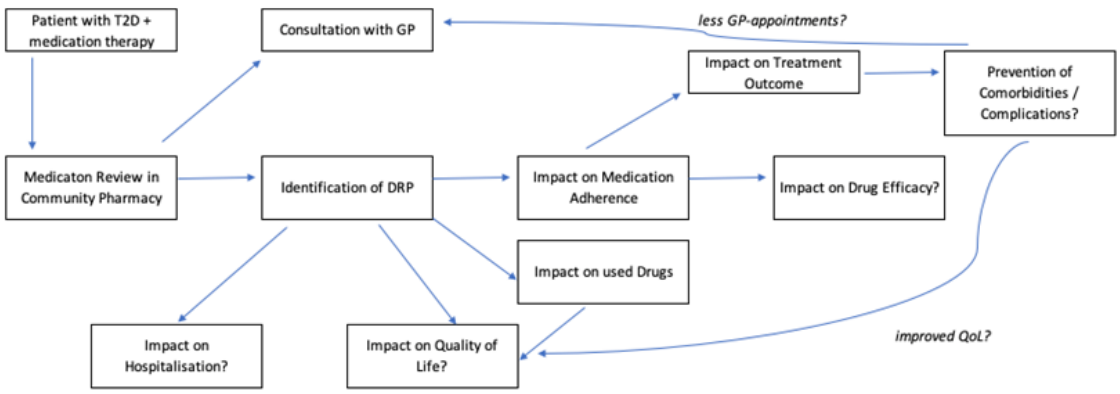

Figure 3 Conceptual model on the impact of medication reviews on the treatment of type 2 diabetes

4.2 Budget Impact Analysis

A BIA is part of a comprehensive economic assessment of new health care interventions and often necessary in health technology assessments. It addresses the financial consequences in the expenditure of a health care system over a short period of time and after the implementation of a new intervention by providing all available knowledge given (Sullivan et al., 2014). Together with a CEA it is often required by reimbursement institutions when planning the adoption of a new

intervention. But other than a CEA, it does not conclude the value of an intervention. Rather it analyses, if the intervention is affordable for the budget holder (U.S. Department of Veterans Affairs, 2022).

In a BIA the current status quo is compared with a new environment after the implementation of an intervention (Sullivan et al., 2014). In this context, the BIA compares current and future costs for the treatment of T2D after the implementation of MRs.

The BIA was executed using *Microsoft® Excel for Mac. Version 16.58*.

4.2.1 Characteristics of Budget Impact Analysis

To successfully perform a BIA while taking all the relevant elements into account, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force has developed a guideline on the principles of good practice (Sullivan et al., 2014). This guideline is the foundation of the BIA and in the following it is described how the elements and characteristics are implemented here.

Perspective

The economic costs are considered from the perspective of the budget holder; being the SHI here. Consequently, only costs incurred by the health insurers are included in this analysis. For the health insurers only direct costs are relevant and included (Müller & Stock, 2019).

Time Horizon

A BIA presents the financial consequences of an intervention for a short period of time with 1 to 5 years being common. In this case, a time horizon of 5 years and annually period will be set. Unlike in a CEA where costs and benefits are discounted to a net present value, this is not recommended in a BIA, as the budget holder is interested in what financial impact is expected at each point in time (Sullivan et al., 2014). Thus, discounting the costs has not been part of this BIA.

Eligible Population

The eligible population is a main component of the BIA as it assesses the population influenced by the new intervention.

As the perspective of the SHI has been considered, only people insured in the SHI are being included. As of January 2022, there are 73 357 859 people insured in the SHI whereby 31 384 597 are under the age of 40 (Bundesministerium für Gesundheit, 2022). The estimation of prevalence and incidence is often described for people over 40 years. To be compatible with these estimations and for the BIA to be more realistic, the total population is assumed to be people insured in the SHI aged 40 and older. The total population is set to be 41 973 262.

Further, the focus is laid on people with T2D who can be identified as such by the community pharmacy. The identification is possible by the identification of antidiabetic drugs in the medication therapy. Thus, the target population is defined as people with T2D who are in medication therapy. The prevalence of T2D insured in the SHI is assumed to be 9.47% (Goffrier et al. 2017). Further, it is assumed that 75% of people with T2D are in medication therapy (Robert Koch-Institut, 2019). Therefore, the target population for year one is 2 981 150.

However, the target population is likely to increase in the following years as additional people who have not been diagnosed with T2D receive a diagnosis. The standardised incidence rate for people aged 40 years and older is assumed to be 1.47% (Goffrier B et al., 2017). For simplicity it is assumed that 1.47% of the total population receive a diagnosis of T2D every year and that the percentage of people in medication therapy remains the same. Thus, every year additional 462 755 people are eligible for MRs.

This target group can be distinguished in various subgroups for example based on the medication therapy (monotherapy, combination, insulin) and based on the participation in a DMP. Unfortunately, there is a lack of data provided on the utilisation of resources of these subtypes and thus, it is not possible to estimate the economic burden of the different subtypes. Accordingly, it does not seem appropriate to distinguish the target group in subgroups. Further, MRs should be provided for people with polypharmacy, however it is unclear how many people with

T2D are in this category. Thus, for simplification it was assumed that every person in medication therapy has polypharmacy.

Intervention Mix and its Costs

Currently, there are no interventions that could be replaced by MRs, but the implementation of MRs may have an impact on the treatment T2D (Figure 3). As there is no evidence on how MRs influence other treatment resources, it is assumed that the implementation of MRs expands the intervention mix of T2D. This means that costs for MRs are additional to the expenditure of other resources. Accordingly, it is necessary to first identify the direct costs for the treatment resources of T2D. In the literature, the direct costs are usually accounted for hospitalisation, medication-supply, outpatient-treatment, and other direct costs (i.e., rehab). It was chosen to distinguish between these sectors and not between different fees for interventions.

There are various cost-illness-studies with different estimations regarding the costs of T2D. As mentioned, the majority of studies estimate the costs to be between € 3 350 and € 5 080 per patient (Müller & Stock, 2019). For the baseline scenario, it was chosen to use the average (€ 4 215 EUR) per patient and year. Further it was assumed that 50% of the costs are caused by hospitalisation, 25% by medication-supply and 18% by outpatient-treatment. The rest is declared as costs for other resources.

Analytic framework description

The analytic framework illustrates the characteristics of the BIA as discussed so far.

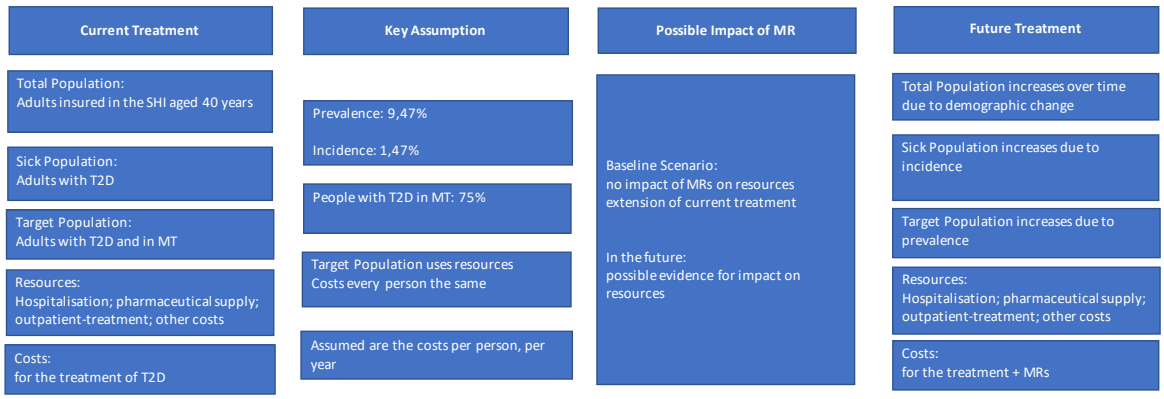

Figure 4 Analytic framework of current and future treatment after implementation of MRs

Analyses and uncertainty

There are various uncertainties in the baseline scenario influencing the outcome of the BIA. First, there is uncertainty regarding the direct costs of T2D and the attribution of different resources. However, the attribution of different resources towards the costs is not relevant, as there is no documented impact of MRs on the usage of these resources. As the total direct costs of T2D need to be considered in the BIA as they might influence the decision to implement MRs or not, two supplementary scenarios have been included being a lower bound scenario (total costs € 3 350) and a higher bound scenario (total costs € 5 080).

Secondly, and for the purpose of this elaboration crucial, there is uncertainty about the utilisation of MRs and the remuneration rate. Therefore, a two-way sensitivity analysis (SA) estimates the cost for the target population (1st year of BIA), and the incidence population (2nd year of BIA), based on changes in the remuneration rate and the utilisation of MRs in the population.

4.2.2 Assumptions of the BIA

As described, there are various uncertainties which make it necessary to describe the main assumptions of the BIA.

- *Reimbursement:* it is assumed that the remuneration of MRs is based on a constant remuneration fee and not on the time spent on MRs.
- *Pharmaceutical supply:* for simplicity, it is assumed that the pharmaceutical supply remains the same even though changes may occur for example in the consumption
- *Utilisation rate:* it is difficult to assume the utilisation of MRs as it depends on various factors which are currently unknown. It can be assumed that there is a yearly incline of utilisation. As there are no similar interventions introduced in pharmacies in Germany and a comparison with other countries is not useful as the role of pharmacists often differ, there are no estimations on the implementation rate. To propose a rather cost-conservative scenario, it is assumed that there is a 20% incline in utilisation of MRs per year. Further, it is assumed that MRs can be performed for a person once a year.

- *Threshold:* as there are no evidence-based benefits for Germany, it is not possible to perform a CEA, to calculate the incremental cost-effectiveness ratio and to assess the willingness-to-pay (WTP). To classify the results, the in VOASG targeted sum of € 150 million is considered as a threshold, meaning that scenarios above this threshold are not financially feasible.

4.3 Expert Interviews

As part of qualitative research, it was chosen to perform expert interviews, as they are an appropriate research method to gain information about a field where publications are rare and where the perception and opinion of people with specific knowledge is advantageous to analyse (Döringer, 2021).

Two expert interviews were conducted with experts from the SHI in February 2022. Both expert interviews were carried out via a online-video platform and were held in German. The experts signed a declaration of consent for the interviews to be recorded and evaluated (see 0).

The experts were selected based on their profession and experience with the remuneration of pharmacies. With around 16 million people, they insure about 20% of the population in the SHI. The first expert, from now on referred to as E1, is a trained pharmacist and is working in the department of pharmaceuticals in one of the largest SHI funds in Germany. The second expert, from now on referred to as E2, is a trained physician and was working as the division manager for the department of pharmaceuticals and selective contracts in the past. He is no longer in the active workforce there.

4.3.1 Development of Questionnaire

It was chosen to develop a guideline interview with the aim to identify different perceptions and views for the same question. Nonetheless, when useful to understand the context or deepen the discussion regarding an aspect, additional questions were asked when appropriate.

Before the development of the guideline, a short review of the literature was performed to understand the current debate regarding the reimbursement of MRs

in Germany and to assess the availability of existent literature. Based on the findings and with regards to the research question here, the following three areas have been defined as areas of interest.

First, it was intended to identify the general perception of implementing MRs in community-pharmacies. In this regard, it was aimed to understand what role MR may have for health care in the future. Further, the expert's opinion on the general conditions was targeted to be established. In this context, it was aimed to identify characteristics which are assumed to be relevant for the eligibility of receiving MRs. The following questions were developed for the first area:

- What role do medication reviews have for health care in the future?
- For which target groups would you offer medication reviews?
- Would you differentiate between rural and urban areas?

Secondly, the next area of interest intended to identify requirements for the reimbursement of MRs. Both requirements at the pharmacy and at the SHI were aimed to be detected. When referring to the developed concept model in Figure 3, the desirable outcomes / benefits are meant to be revealed. Here, the following questions were developed:

- What requirements must a pharmacy fulfil to be reimbursed for medication reviews by the SHI provider?
- What requirements must a health insurance company fulfil to be able to reimburse MRs?
- What benefits should medication reviews have for a person so that they can be reimbursed by the SHI provider?

The last area of interest was to determine the framework conditions for the remuneration of MRs including the willingness-to-pay (WTP). The following questions were developed:

- What would you be willing to pay for a medication remuneration?
- How would you structure the remuneration of medication reviews?
- Should there be an annual minimum quantity per pharmacy and / or a maximum quantity per insured person?

It must be stressed that the focus of the expert interview was not on the patient group of people with T2D. Rather, it was intended to identify the general requirements and to identify whether the assumptions made beforehand that people with T2D are possibly an eligible patient group to receive MRs are also in accordance with the view of the experts.

4.3.2 Analysis Procedure

To manifest the main content answering the questions, a qualitative content analysis was performed by developing categories on the statements of the experts. This approach corresponds to the inductive category formatting by (Mayring, 2014) which was chosen as the nature of this elaboration is rather explorative and allows the presentation of the results in the way suitable for this elaboration.

The inductive category formatting by Mayring consists of eight steps (Figure 5). As only two expert interviews with a manageable length of transcript were analysed, step 4 has been disregarded. For the same reason, a frequency analysis has not been performed. Other than that, the steps of this analysis approach have been followed.

Before performing the analysis, the expert interviews have been transcribed, omitting filler words or digressions that were not relevant to the context and purpose of the interview. Upon request, E1 was sent the interview in advance to rule out misunderstandings.

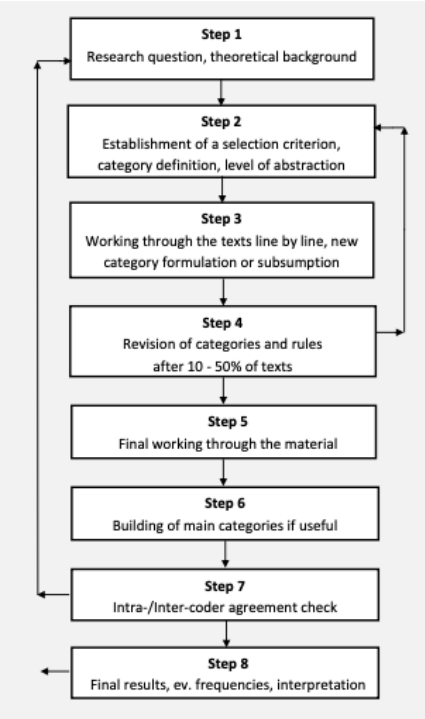

Figure 5 Steps of the inductive category formatting by Mayring (2014 p. 80)

An important consideration of the inductive category formatting is the definition and abstraction of categories as this is the foundation for the development of categories (Mayring, 2014). Table 3 describes the definitions applied in this study.

Content-analytical units	
Cod ng un t	C ear semant c e ements n the nterv ews
Context un t	Transcr pt of nterv ews
Record ng un t	Two expert nterv ews (E1, E2)
Category definition	1. ro e of MRs, mp ementat on, nc us on cr ter a to be e g b e to rece ve MRs 2. requ rements for the remunerat on
Level of abstraction	1. Concrete c ass f cat ons n pat ent groups 2. Concrete c ass f cat ons n requ rements

Table 3 Defined foundation to develop categories

The inductive category formatting has been applied for the first two interests of areas. As the third area of interest does not provide the opportunity to build

categories, it was chosen to not analyse the results based on this approach. Therefore, the opinions of the experts have been summarised.

For the coding of the first two areas of interest, the different categories were coloured and highlighted using the worksheet of *Microsoft® Excel for Mac. Version 16.58*.

5 Results

The purpose of this chapter is to describe the results of the applied methodologies. First, the results towards the first research question are being illustrated by describing and summarising the findings of the BIA.

To provide the results answering the second research question, the findings and categories of the expert interviews are being delivered.

5.1 Results of Business Impact Analysis

The financial implications of the reimbursement of MRs depend on the size of the target population, the reimbursement rate, the utilisation rate in the population, and possible savings in other sectors.

Table 4 summarizes the input parameters for the BIA. The assumptions regarding the variables can be found in the description of the methodology in 4.2.1. It was chosen to perform the calculation with a remuneration rate of € 60. This remuneration rate is advised by the ABDA and comparable to the rate used in current real-world projects and community-pharmacies.

The applied utilisation rate and total target population of the BIA are described in Table 5. The assumptions regarding the utilisation rate can be found in 4.2.2. Further, the total target population has been calculated by adding the incidence population to the target population.

Parameter	Baseline	Lower	Upper
Population			
Total Population in the SHI without children	41 973 262		
Incidence of T2D in adults	1.47 %		
Prevalence of T2D in adults	9.47 %		
% People in medication therapy	75 %		
Target population	2 981 150		
Costs for the treatment of T2D p.P.	4 215 €	3 350 €	5 080 €
Out-patient treatment (18%)	759 €	603 €	914 €
Hospitalisation (50%)	2 108 €	1 675 €	2 540 €
Drug-supply (25%)	1 054 €	838 €	1 270 €
Other costs (7%)	295 €	235 €	356 €
Remuneration per MR in EUR	60 €		

Table 4 Input parameter for the Business Impact Analysis

Year	Utilisation Rate	Total target population
Year 1 / 2022	10%	2 981 150
Year 2 / 2023	30%	3 443 905
Year 3 / 2024	50%	3 906 660
Year 4 / 2025	70%	4 369 415
Year 5 / 2026	90%	4.832.170

Table 5 Assumption of utilisation rate and total target population per year

The costs have been calculated with the following formula:

Costs of MR (t) = Total target population (t) x Utilisation Rate (t) x Remuneration Rate

The additional costs caused by the reimbursement of MRs are € 641 529 830 for five years. The additional costs for MRs are € 117 199 841 in 2024 and € 183 515 496 in 2025. Therefore, the considered threshold of € 150 million has been reached between 2024 and 2025. This means that the remuneration is no longer feasible in 2025.

Including the costs for the MRs, the total costs for the treatment of T2D would be € 82 974 418 005 for five years – of which 0.77% are due to MRs (Table 6).

In the lower bound scenario, the total costs are € 66 078 107 621 with costs for MRs being almost 1% (0.0097) of the total costs for the five years (Table 7). In the upper

bound scenario, the treatment of T2D leads to costs of € 99 870 728 390 (Table 8). Comparing the lower and upper scenario, the difference of the treatment costs for T2D amount to € 33 792 620 769.

	2022	2023	2024	2025	2026	Total costs
Costs for MR BI	17.886 906	61.990.311	117.199 841	183.515.496	260.937 277	641.529.830
Costs op-visits	2.261.799 213	2.612.891.594	2 963.983 974	3.315.076.355	3.666.168.735	14.819.919.872
Costs hospitalisation	6.282.775 592	7.258.032.205	8 233.288 818	9.208.545.430	10.183.802 043	41.166.444.088
Costs drug-supply	3.141.387.796	3.629.016.103	4.116.644.409	4.604.272.715	5.091.901 021	20.583.222.044
Other Costs	879.588 583	1.016.124.509	1.152.660.434	1.289.196.360	1.425.732 286	5.763.302.172
Total Costs w/o MR	12.565.551.185	14.516.064.410	16.466.577.635	18.417.090.860	20.367.604 085	82.332.888.176
Total Costs with MR	12.583.438 091	14.578.054.721	16 583.777.476	18.600.606.356	20.628.541 362	82.974.418.005

Table 6 BIA baseline case scenario

	2022	2023	2024	2025	2026	Total costs
Costs for MR BI	17.886.906	61.990.311	117.199.841	183.515.496	260.937.277	641.529.830
Costs op-visits	1.797.634.013	2.076.675.407	2.355.716.800	2.634.758.194	2.913.799.588	11.778.584.002
Costs hospitalisation	4.993.427.814	5.768.542.796	6.543.657.779	7.318.772.762	8.093.887.744	32.718.288.895
Costs drug-supply	2.496.713.907	2.884.271.398	3.271.828.890	3.659.386.381	4.046.943.872	16.359.144.448
Other Costs	699.079.894	807.595.991	916.112.089	1.024.628.187	1.133.144.284	4.580.560.445
Total Costs w/o MR	9.986.855.627	11.537.085.593	13.087.315.558	14.637.545.524	16.187.775.489	65.436.577.791
Total Costs with MR	10.004.742.533	11.599.075.903	13.204.515.399	14.821.061.020	16.448.712.766	66.078.107.621

Table 7 BIA lower bound scenario

	2022	2023	2024	2025	2026	Total costs
Costs for MR BI	17.886.906	61.990.311	117.199.841	183.515.496	260.937.277	641.529.830
Costs op-visits	2.725.964.414	3.149.107.781	3.572.251.148	3.995.394.515	4.418.537.883	17.861.255.741
Costs hospitalisation	7.572.123.371	8.747.521.614	9.922.919.856	11.098.318.098	12.273.716.341	49.614.599.280
Costs drug-supply	3.786.061.686	4.373.760.807	4.961.459.928	5.549.159.049	6.136.858.170	24.807.299.640
Other Costs	1.060.097.272	1.224.653.026	1.389.208.780	1.553.764.534	1.718.320.288	6.946.043.899
Total Costs w/o MR	15.144.246.742	17.495.043.227	19.845.839.712	22.196.636.197	24.547.432.682	99.229.198.561
Total Costs with MR	15.162.133.648	17.557.033.538	19.963.039.553	22.380.151.693	24.808.369.958	99.870.728.390

Table 8 BIA upper bound scenario

5.1.1 Target Value Analysis

As the results show, the remuneration of MRs would not be feasible for every year of the five-year period when considering € 150 million as a threshold.

To identify the tipping point in which the reimbursement is not feasible, a target value analysis was performed. The idea is to find the remuneration rate where costs that equal € 150 million are reached in the respective total target population. For the target value analysis, it is assumed that the utilisation rate is 100%.

Table 9 shows the results for the target remuneration rate for each year. The total target population found in Table 5 was applied. It is shown that with the increase of the eligible population, the possible remuneration rate decreases by roughly 40% from € 50.32 to € 31.04 over the 5-year period.

	2022	2023	2024	2025	2026
Costs for MR	150 000 000 €	150 000 000 €	150 000 000 €	€150 000 000 €	150 000 000 €
Population	2 981 150	3 443 905	3 906 660	4 369 415	4 832 170
Remuneration Rate	50.32 €	44.56 €	38.40 €	34.33 €	31.04 €

Table 9 Target value analysis for remuneration rate

5.1.2 Sensitivity Analysis

As there is uncertainty regarding the utilisation of MRs in the population and the remuneration rate of MRs, a two-way sensitivity analysis was performed to study the total costs of MRs depending on the utilisation and the remuneration rate. The two-way sensitivity analysis has been performed each for the target population and for the incidence population.

The utilisation rate is not only a parameter describing the utility or implementation of the service in the population but can also be translated into how many individuals are receiving the service in absolute numbers. Accordingly, it is necessary to provide a short overview on how the utilisation rates translate into the size of the population (Table 10).

Utilization Rate	Target Population	Incidence Population
5%	149.058	23.138
10%	298.115	46.276
15%	447.173	69.413
20%	596.230	92.551
25%	745.288	115.689
30%	894.345	138.827
35%	1.043.403	161.964
40%	1.192.460	185.102
45%	1.341.518	208.240
50%	1.490.575	231.378
55%	1.639.633	254.515
60%	1.788.691	277.653
65%	1.937.748	300.791
70%	2.086.806	323.929
75%	2.235.863	347.066
80%	2.384.921	370.204
85%	2.533.978	393.342
90%	2.683.036	416.480
95%	2.832.093	439.617
100%	2.981.151	462.755

Table 10 Target and incidence population depending on the utilisation rate

For the two-way-sensitivity analyses performed on the target population (Table 11), the threshold is again set to be € 150 million (red). Further, a scaling has been applied: costs up to € 50 million were considered acceptable (green), costs between € 50 - € 100 million limited acceptable (yellow) and between € 100 – 150 million very limited acceptable (orange). For the incidence population (Table 12), the same logic has been applied with the boundaries being set to €7 761 352, €15 522 703 and €23 284 055[1].

Based on this classification, a remuneration rate of € 10 would be acceptable and a rate of up to € 30 limited acceptable for every utilisation rate. A rate of € 60 would not be feasible when a utilisation rate of more than 80% is considered. Talking in populations, in that scenario only 80% of the target population – in numbers 2.384.920 patients - would be able to receive a MR.

Considering a utilisation rate of 100%, the costs for MRs in the target population would be between € 29 811 509 and € 238 492 075 (Table 11) and in the incidence population between € 4 627 552 and € 37 020 417 (Table 12). A remuneration rate of € 50 would be the highest feasible option in this scenario.

[1] The boundaries were calculated by dividing the respective threshold / total population of table 9. The ratio was then multiplied with the incidence population.

The scenario with the lowest costs generated over the 5-year-perspective of the BIA would be achieved when a remuneration rate of € 10 and a utilisation rate of 5% is considered. The total costs would amount to € 9 766 653 and the total target population would be 241 610 for the 5-year-period. Reviewing a one-year perspective, additional costs total to at least € 1 490 575.

	Remuneration Rate							
298.115.093 €	10,00 €	20,00 €	30,00 €	40,00 €	50,00 €	60,00 €	70,00 €	80,00 €
5%	1.490.575 €	2.981.151 €	4.471.726 €	5.962.302 €	7.452.877 €	8.943.453 €	10.434.028 €	11.924.604 €
10%	2.981.151 €	5.962.302 €	8.943.453 €	11.924.604 €	14.905.755 €	17.886.906 €	20.868.057 €	23.849.207 €
15%	4.471.726 €	8.943.453 €	13.415.179 €	17.886.906 €	22.358.632 €	26.830.358 €	31.302.085 €	35.773.811 €
20%	5.962.302 €	11.924.604 €	17.886.906 €	23.849.207 €	29.811.509 €	35.773.811 €	41.736.113 €	47.698.415 €
25%	7.452.877 €	14.905.755 €	22.358.632 €	29.811.509 €	37.264.387 €	44.717.264 €	52.170.141 €	59.623.019 €
30%	8.943.453 €	17.886.906 €	26.830.358 €	35.773.811 €	44.717.264 €	53.660.717 €	62.604.170 €	71.547.622 €
35%	10.434.028 €	20.868.057 €	31.302.085 €	41.736.113 €	52.170.141 €	62.604.170 €	73.038.198 €	83.472.226 €
40%	11.924.604 €	23.849.207 €	35.773.811 €	47.698.415 €	59.623.019 €	71.547.622 €	83.472.226 €	95.396.830 €
45%	13.415.179 €	26.830.358 €	40.245.538 €	53.660.717 €	67.075.896 €	80.491.075 €	93.906.254 €	107.321.434 €
50%	14.905.755 €	29.811.509 €	44.717.264 €	59.623.019 €	74.528.773 €	89.434.528 €	104.340.283 €	119.246.037 €
55%	16.396.330 €	32.792.660 €	49.188.990 €	65.585.321 €	81.981.651 €	98.377.981 €	114.774.311 €	131.170.641 €
60%	17.886.906 €	35.773.811 €	53.660.717 €	71.547.622 €	89.434.528 €	107.321.434 €	125.208.339 €	143.095.245 €
65%	19.377.481 €	38.754.962 €	58.132.443 €	77.509.924 €	96.887.405 €	116.264.886 €	135.642.367 €	155.019.849 €
70%	20.868.057 €	41.736.113 €	62.604.170 €	83.472.226 €	104.340.283 €	125.208.339 €	146.076.396 €	166.944.452 €
75%	22.358.632 €	44.717.264 €	67.075.896 €	89.434.528 €	111.793.160 €	134.151.792 €	156.510.424 €	178.869.056 €
80%	23.849.207 €	47.698.415 €	71.547.622 €	95.396.830 €	119.246.037 €	143.095.245 €	166.944.452 €	190.793.660 €
85%	25.339.783 €	50.679.566 €	76.019.349 €	101.359.132 €	126.698.915 €	152.038.698 €	177.378.481 €	202.718.263 €
90%	26.830.358 €	53.660.717 €	80.491.075 €	107.321.434 €	134.151.792 €	160.982.150 €	187.812.509 €	214.642.867 €
95%	28.320.934 €	56.641.868 €	84.962.802 €	113.283.735 €	141.604.669 €	169.925.603 €	198.246.537 €	226.567.471 €
100%	29.811.509 €	59.623.019 €	89.434.528 €	119.246.037 €	149.057.547 €	178.869.056 €	208.680.565 €	238.492.075 €

Utilization Rate

Table 11 Two-Way Sensitivity Analysis on utilisation and remuneration rate of MRs for target population

	Remuneration Rate							
46.275.521 €	10,00 €	20,00 €	30,00 €	40,00 €	50,00 €	60,00 €	70,00 €	80,00 €
5%	231.378 €	462.755 €	694.133 €	925.510 €	1.156.888 €	1.388.266 €	1.619.643 €	1.851.021 €
10%	462.755 €	925.510 €	1.388.266 €	1.851.021 €	2.313.776 €	2.776.531 €	3.239.286 €	3.702.042 €
15%	694.133 €	1.388.266 €	2.082.398 €	2.776.531 €	3.470.664 €	4.164.797 €	4.858.930 €	5.553.063 €
20%	925.510 €	1.851.021 €	2.776.531 €	3.702.042 €	4.627.552 €	5.553.063 €	6.478.573 €	7.404.083 €
25%	1.156.888 €	2.313.776 €	3.470.664 €	4.627.552 €	5.784.440 €	6.941.328 €	8.098.216 €	9.255.104 €
30%	1.388.266 €	2.776.531 €	4.164.797 €	5.553.063 €	6.941.328 €	8.329.594 €	9.717.859 €	11.106.125 €
35%	1.619.643 €	3.239.286 €	4.858.930 €	6.478.573 €	8.098.216 €	9.717.859 €	11.337.503 €	12.957.146 €
40%	1.851.021 €	3.702.042 €	5.553.063 €	7.404.083 €	9.255.104 €	11.106.125 €	12.957.146 €	14.808.167 €
45%	2.082.398 €	4.164.797 €	6.247.195 €	8.329.594 €	10.411.992 €	12.494.391 €	14.576.789 €	16.659.188 €
50%	2.313.776 €	4.627.552 €	6.941.328 €	9.255.104 €	11.568.880 €	13.882.656 €	16.196.432 €	18.510.209 €
55%	2.545.154 €	5.090.307 €	7.635.461 €	10.180.615 €	12.725.768 €	15.270.922 €	17.816.076 €	20.361.229 €
60%	2.776.531 €	5.553.063 €	8.329.594 €	11.106.125 €	13.882.656 €	16.659.188 €	19.435.719 €	22.212.250 €
65%	3.007.909 €	6.015.818 €	9.023.727 €	12.031.636 €	15.039.544 €	18.047.453 €	21.055.362 €	24.063.271 €
70%	3.239.286 €	6.478.573 €	9.717.859 €	12.957.146 €	16.196.432 €	19.435.719 €	22.675.005 €	25.914.292 €
75%	3.470.664 €	6.941.328 €	10.411.992 €	13.882.656 €	17.353.321 €	20.823.985 €	24.294.649 €	27.765.313 €
80%	3.702.042 €	7.404.083 €	11.106.125 €	14.808.167 €	18.510.209 €	22.212.250 €	25.914.292 €	29.616.334 €
85%	3.933.419 €	7.866.839 €	11.800.258 €	15.733.677 €	19.667.097 €	23.600.516 €	27.533.935 €	31.467.355 €
90%	4.164.797 €	8.329.594 €	12.494.391 €	16.659.188 €	20.823.985 €	24.988.782 €	29.153.578 €	33.318.375 €
95%	4.396.175 €	8.792.349 €	13.188.524 €	17.584.698 €	21.980.873 €	26.377.047 €	30.773.222 €	35.169.396 €
100%	4.627.552 €	9.255.104 €	13.882.656 €	18.510.209 €	23.137.761 €	27.765.313 €	32.392.865 €	37.020.417 €

Utilization Rate

Table 12 Two-Way Sensitivity Analysis on utilisation and remuneration rate of MRs for incidence population

5.2 Results of Expert Interviews

The results of the expert interviews give insights on how experts from the SHI assess MRs. In the following, the results for each area of interest are summarised by providing an overview of the identified categories with reference to the respective text passage.

5.2.1 Implementation of Medication Reviews

Both E1 and E2 had difficulties in answering the question what role MRs may have for health care while mentioning that MRs are already being performed in Germany but also describing challenges and uncertainties regarding the general implementation of MRs in Germany (Table 13).

Main categories	Subcategories	Example
Ev dence	Ident f cat on of pat ent groups	E1 p. 69 . 7
	Impact of med cat on rev ews	E1 p. 70 . 44
	Eva uat on of med cat on rev ews	E1 p. 69 . 11
Conduct on	Profess on conduct ng med cat on rev ews	E2 p. . 5
	Generat ng (measurab e) benef ts	E1 p. 69 . 8
Layout	Ass gnment of the pat ent to the correct program	E1 p. 69 . 11
	Access to program	E1 p. 70 . 53
	D g ta sat on of e ectron c records	E1 p. 72 . 128

Table 13 Challenges and considerations of the implementation of medication reviews

E1 outlined challenges including the lack of evaluation and subsequently the lack of knowledge regarding the impact of MRs and the identification of eligible patient groups. He explained that *“evidence-based proof of which intervention leads to which positive benefit would be good and a starting point for offering such services in a meaningful way”* (E1 p. 70 ll. 40) and that in his opinion *“we are still a little bit away from having a clear picture of what the populations are that can really benefit the most from this”* (E1 p. 70 ll. 40).

In addition, E2 questioned the need for this kind of service and described a project he was involved in where patients with polypharmacy received a check of medication by their physicians. From the results of this service, he concluded that *"nothing came out for the number of patients affected"* (E2 p.75 ll. 20).

E2 also raised the question whether the pharmacy is the right institution to perform MRs as *"[…] neither the pharmacist nor the doctor can claim to have an overview of everything"* (E2 p. 75 l. 7). He explained that the pharmacist is *"nothing more than the salesman who hands the preparation over the table and, in the best case, advises the patient how to take it and what he should pay attention to"* (E2 p. 78 ll. 96).

E2 stated that "the only ones who have an overview of everything are the health insurance companies." (E2 p. 75 l. 7) but he could imagine that if there would be an electronic solution which catches *"every prescription that is made, no matter by whom, and could check beforehand through an intelligent system whether there are contradictions in the prescription or overlaps […] then […] that could be the pharmacist who provides that, because that's all checked beforehand."* (E2 p. 79 ll. 142). Nevertheless, he stresses that *"the pharmacist still has the problem that he can't change it [medication] himself"* (E2 p. 79 l. 149).

Referring to the electronic solution, both experts described that SHI funds may have an important role for the implementation of MRs when electronic tools like the electronic health report (EHR) or the electronic prescription are widely implemented and used. They think that digitalisation simplifies the identification of patients and enables the SHI to create advantages by automatization processes:

> *That is, if we really knew that the pharmaceutical services for medication XY lead to the patient being in the hospital less, then this could also be played back to the patient in his ePA. The patient decides whether they want value-added services to be offered to them. Based on the data we know from his prescriptions; he could decide in favor of such a service and automatically receive a note on pharmaceutical services in his ePA.* (E1 p. 72 ll. 126)
>
> *[...] And when you have experience, you can expand that if the electronic prescription exists and you make sense of it. Then I don't need to pay for it, because then I can do it electronically and with the stored artificial*

intelligence, I can identify the patients with critical combinations […], and I could send them somewhere very specifically where the review is then performed. (E2 p. 76 ll. 42)

In addition, both experts think that there might be beneficial synergies when providing the option to manually add self-medication:

One example: there is no self-medication in the health insurance data. The prescribed medications are documented. If the patient wants, he can find them in his EHR. Synergies can be imagined here: if the patient inserts the information on self-medication in the electronic patient file and at the same time has an allergy to this medication stored in the EHR, a warning can be issued. This could then definitely result in a measurable added value for the patient. (E1 p. 72 ll. 103)

You would have to offer at some point that the person could add that manually, so to speak. We could also have a meaningful EHR, which we don't have either, where the patient could deposit that. Then you could add that information there. (E2 p. 76 ll. 51)

With regards to the identification of relevant patient groups, both experts think that people with multimorbidity and polypharmacy are eligible beneficiaries of MRs (E1 p. 70 l. 36, E2 p. 76 l. 37). E2 could also imagine that age might be considered as a requirement but also wonders whether there are significant differences between a younger and older person when both have polypharmacy (E2 p. 76 l. 42). Furthermore, E1 thinks that taking specific drugs could be an indication for MRs as well:

However, one must certainly also ask oneself whether there are specific drugs that are particularly "sensitive", i.e., where a high degree of adherence is necessary on the one hand, but which are also highly potent, for example the more modern cancer drugs that are taken, i.e., oral cancer drugs.
(E1 p. 70 l. 35)

The experts disapprove with an eligibility criterion of living in rural or urban areas. However, E1 thinks that differences regarding the accessibility of service needs to be considered:

So that means in rural areas, where perhaps providers are rarer for such services […], what kind of offer do I have to create there so that I can get in touch with this service provider? […] Are there hybrid models between analogue, i.e., personal contact, digital contact, an app? I would ask myself that question, simply because of the structural differences between urban and rural areas. (E1 p. 70 ll. 53)

5.2.2 Requirements for the Remuneration

The categories for the identification of requirements for the reimbursement of MRs are summarised in Table 14. Generally, the categories can be considered as further necessities for the successful implementation of MRs as remuneration is only advisable when MRs are successfully conducted.

Categories	**Subcategories**	**Example**
F rst stage	Documentat on	E1 p. 72 . 121
	Start of educat ona tra n ng	E1 p. 70 . 64
Second stage	Equ pment and fac t es	E1 p. 71 . 69
	D g ta sat on n pharmacy	E1 p. 72 . 98
Overarch ng necess ty	Know edge and ab ty to dent fy re evant pat ent groups	E1 p. 72 . 124

Table 14 Requirements for the reimbursement of medication reviews

According to E1, two phases should be distinguished. In a first phase, pharmacists and SHI should gain experience on how to conduct MRs:

> That's where the requirements can be a little more open to allow many pharmacies to participate in a concept like this. In this scenario, we can first learn and practice to implement aspects that are still very similar to consultation, but accordingly already go in the direction of medication reviews. I would say that in the initial phases, we must first approach this from both sides and gain experience. (E1 p. 72 ll. 116)

Further, E1 thinks that *"in the start-up phase, to get this up and running, there must be sufficient documentation security. This can also be an Excel spreadsheet."* (E1 p. 72 l. 122). He explains that sufficient documentation is also foundation for the evaluation of impact.

Additionally, E1 thinks that it is useful that pharmacists should undergo an educational training, but he stressed that the all-encompassing knowledge does not need to be there at the beginning:

> *Medication review training for pharmacists - Athena is one such example. It makes sense that there should be another introduction to the specific handling of medication reviews. Perhaps not everything has to be available at the beginning, but the path should go in the direction that one has also refreshed the corresponding know-how and is familiar with the processes and structures of the analysis. This can also be built up on a modular basis.* (E1 p. 70 ll. 64)

In the long-term and in regard to scalability, E1 thinks that it is necessary for the pharmacy to have enough trained employees with the ability to perform MRs (E1 p. 58)

E1 considers that in the long-term and in an ideal situation, pharmacies, and the SHI "*should know exactly what effect an intervention has […] [and] that a pharmacy must be able to identify these insured persons appropriately, or we must be able to inform patients about such offers within the framework of data protection law."* (E1 p. 72 ll. 123).

Further, E1 explains that *"in the long term, digitalisation will definitely be required*" (E1 p. 72 l. 93). He proceeds that *"there are also programs on the market that already map this extensively."* (E1 p. 72 ll. 96)

5.2.3 Financial Implications and Willingness-to-Pay

The aim of the third area was to identify the WTP. First, it was analysed what benefits are needed to be achieved to remunerate MRs. Both experts agree that patient benefits should be an outcome of MRs:

> *From my point of view, the only benefit that something like this should have, is an individual patient benefit, that they're better off afterwards because they have fewer side effects, they're better off because they have fewer complication […].* (E2 p. 79 ll. 154)

Further, E1 elaborates that not only patient-reported outcomes should be included but also QoL and medical-economic outcomes:

> *But these should be measurable, and we should also ask: is the benefit perceived by the patient? So that is a minimum criterion. […] Patient-reported outcomes as well as patient satisfaction are certainly points. Quality of life is also a point that is important for insured persons, where you also no longer have an abstract construct, but can be measured via relevant questionnaires. In this way, it is possible to measure whether the quality of life has been positively influenced, for example. Medical-economic outcomes are also included.* (E1 p. 73 ll. 141)

With regards to the medical-economic outcomes and savings, the experts have a different opinion. While E1 thinks that savings can occur and should be considered, E2 does not think that savings are likely to occur:

> *He benefits from this if it can be prevented. But and this closes the circle to the benefit element for the insured community, costs are of course also saved. Unnecessary costs that also cause the patient suffering. This is the loop that lies behind it.* (E1 p. 73 l. 155)

> *So, it has to be something that is relevant to the patient. As I said, you don't save anything by doing this. So, anyone who does this to save money is overlooking the costs that it causes.* (E2 p. 80 l. 159)

On the other side, E2 could imagine that when not thinking about the SHI, savings of resources could be considered when calculating a remuneration rate:

> *That is extremely difficult. If it wasn't SHI, I would say, let's see how much resources he used up before because of his side effects, and if we see savings of 10 percent over the next two years, we'll pay that. But of course, these are considerations that don't work in SHI, because I have to have a fixed fee schedule.* (E2 p. 80 ll. 170)

In summary, it was difficult to estimate the WTP as there is a lack of evidence-based knowledge on the benefits of MRs:

> *Once we have the experience of what the benefits are in terms of quality of life, patient satisfaction, avoidance of medical events, i.e., hospitalisation or asthma attacks, and perhaps even savings in various cost dimensions, then we could consider again what such a price tag would be.* (E1 p. 74 ll. 171)

E1 opinions that the reimbursement of MRs does not need to be fully cost covering in individual cases. He proposes that it is necessary for the pharmacist to provide the service in a high scalability – at least in the long term. Further, he assumes that a small incentive should be considered at the beginning:

> *The question of who will benefit from the offer is not yet clear. We now assume that there should be a small incentive, at least at the beginning. This will certainly not fully cover costs in the pharmacy, but from our logic it does not have to be fully cost-covering in individual cases either. The important thing is that a scalable process is established in the pharmacy.*
> (E1 p. 74 ll. 163)

In the opinion of E2 would like to condense the service for a few. However, it is not possible to reconstruct, if he thinks it should be provided for a few people or if the service is provided by a few. Further, it is not clear, if this sum is considered adequate for a pharmacy-based MR or for a physician-based MR:

> *I think maybe 10 to 15 euros would be adequate. But I would like to condense it very much to very few and then you can of course go beyond that*. (E2 p. 80 ll. 175)

Regarding the minimum and maximum quantity, E2 considers maximum quantity limits to be useful but minimum quantity limits rather not:

> *I think once or twice a year is too often. You can't do a medication review with every quarterly prescription unless you automate it. As long as you put manual work into it, it's too expensive and not very profitable. […] Minimum quantity is a question as well. Does that potentially lead to medication reviews being done on people where you could do it, but it's pointless for you to do it? Maximum quantity limits definitely. I would be very cautious about minimum quantity limits.* (E2 p. 80 ll. 182)

6 Discussion

The aim of this thesis is to examine the financial feasibility of reimbursing MRs performed for people with T2D in community pharmacies. To discuss the findings, the results of the BIA will be integrated into the current research and political debate. As there is still a lot of uncertainty regarding the framework of remuneration, various considerations are discussed.

Based on the findings of the expert interviews, recommendations for the remuneration of MRs will be outlined. As the lack of evidence-based benefits has been identified as a main challenge but long-term requirement for the remuneration of MRs, there is the need for more research into the cost-effectiveness of this intervention. A CEA is not part of this elaboration but crucial to estimate the financial implications comprehensively. Hence, recommendations and assumptions for the development of CEA are being proposed in the discussion.

Afterwards, strengths and limitations of this study are being described. Finally, the implications for future research and for the practice are presented.

6.1 Findings of the Business Impact Analysis

The results of the BIA indicate that expenditures attributed to the reimbursement of MRs for T2D would go into the millions. Considering the objective of the VOASG and the proposed budget presented there, the reimbursement of MRs is feasible - at least when choosing the right remuneration rate and size of population eligible for this service.

There are currently, no known other publications estimating the financial implications of implementing and reimbursing this service in German community-pharmacies or for the patient group of people with T2D. Neither BIA nor other economic studies have been found.

Even when considering international publications, informative studies are rare. Only one study has been found where a BIA has been applied to measure the financial consequences of bi-weekly MRs performed in an Irish university hospital (Kearney et al., 2018). The results indicate that adopting bi-weekly MRs would lead to annual costs between € 6.04 – € 6.39 million and annual net benefits between € 29.5 - € 31.2 million over a 5-year period. However, because of the different settings and

the assumed frequency of performing MRs, these results can hardly be considered for comparison.

In addition, a health technology review of pharmacist-led MRs performed in Canada found that spending for this service differs considerably between different Canadian jurisdictions with a range of less than $ 1 million to up to more than $ 16 million (Harris & Argáez, 2021). The authors suggested that there are differences in the rate of performing MRs in different Canadian jurisdictions (Harris & Argáez, 2021) which highlights in return the need to include the utilisation rate in this BIA.

There are several studies assessing the cost-effectiveness of MRs, but the results remain inconclusive. A systematic literature review showed that an effect has been frequently found on drug-related outcomes, but no effect has been found towards a change in QoL and clinical outcomes such as mortality and hospital admissions. Further, the evidence for an effect on economic outcome measures was inconclusive (Huiskes et al., 2017). Similarly, although being already widely implemented, no cost-effectiveness evidence was found in the Canadian setting (Harris & Argáez, 2021).

In Germany, there is also a lack of cost-effectiveness evidence. On top of that, results from other countries are not generalizable to the German health system as the role of the pharmacist, the definition of MRs and the underlying conditions differ. This emphasizes the need for CEA to be performed in Germany.

6.1.1 Integration of the Findings into the Current Political Debate

As the integration of this study's results into the current research is limited to available publications, a closer look at the current political debate seems fruitful and necessary.

Considering the VOASG, additional € 150 million are aimed to be spent annually to fund pharmaceutical services. When treating this sum as a threshold and using the results of Table 11, a maximum of € 50 per MR can be used to reimburse this service for people with T2D in year 1. At first glance, this remuneration rate seems legitimate as it does not deviate considerably from advised remuneration rates. However, when taking a closer look at the framework of the VOASG, some challenges surface, which need to be discussed.

First, the targeted € 150 million are not only for the reimbursement of MRs but for other pharmaceutical services as well. Therefore, this sum cannot be spent solely on MRs which implicates that the expenditure attributed to MRs must be lower than an annual € 150 million. Currently, it is not known what other pharmaceutical services are going to be reimbursed within the scope of VOASG and as a matter of fact, it is not even clear whether MRs are a part of the pharmaceutical services to be provided and reimbursed in the future. This fact leads to the problem that it is not known what the actual threshold for the financial feasibility of reimbursing MRs is.

Secondly, even if assumed that MRs are the only pharmaceutical service considered, a maximum remuneration rate of € 50 would only be applicable in the first year. In the second year, where the total target population increases because of the additional incidence population, a remuneration rate of € 50 would exceed the € 150 million. Accordingly, an approach as described in the target value analysis should be considered in this case.

Thirdly, this elaboration estimated the financial implications of MRs for people with T2D aged 40 years and older. Other patient groups have not been included although they may be eligible for MRs. Taking the demographic shift and increasing prevalence of multimorbidity into account, a constant remuneration rate of € 50 would lead to substantially higher expenses than € 150 million in the future.

The current approach to remunerate additional pharmaceutical services raises questions as well. As described, for every prescribed pharmaceutical package, the pharmacist receives additional € 0.20. The additional fee is part of a budget which is going to be distributed by the data centres of pharmacies (Apothekenrechenzentren) until another agreement has been reached (Sucker-Sket, 2022). However, as there is currently still discussion regarding the allocation, it is not known how the budget is going to be distributed and how a service-based remuneration will be implemented (Rohrer, 2020).

Under assumption that the budget for pharmaceutical services is solely dependent on the additional fee received per prescribed package, there would be a budget cap. When reviewing the year 2020, this remuneration approach would have led to a budget of € 139 million[2] for pharmaceutical services. But this budget is smaller than

[2] Calculation: prescribed packages attributed to people insured in the SHI (695 million) x € 0,20

the intended € 150 million and accordingly, it would not have been possible to contemplate a remuneration rate of € 50 per MR – even when MRs were the only pharmaceutical service.

Continuing this thought, the budget for pharmaceutical services could change every year as it depends on dispensing prescribed medication packages. Therefore, it could be imagined that the remuneration rate for MRs and other pharmaceutical services will be adjusted annually which leads again to more administrative expenditures. Further, it is questionable whether pharmacists would agree to changing remuneration rates as the workload remains the same. If considering an annual correction, the remuneration rate must be set using the dispensing figures of the previous year as it is not possible to estimate a maximum remuneration rate without knowing the budget. But this raises further questions including what happens if the budget is exhausted. Should there be a graduation of compensation based on reaching a certain revenue value e.g., after performing a certain maximum level of MRs? What happens if there are substantially more MRs performed in the following year?

These considerations show the complexity of the current negotiations regarding the reimbursement of pharmaceutical services between the DAV and the GKV-SV. As of February 2022, the parties were not able to reach an agreement on the general conditions for the implementation of VOASG (Sucker-Sket, 2022). But the need for a timely agreement is clearly shown when integrating the findings of this study into the current political debate.

6.1.2 Further Considerations regarding the Reimbursement

The uncertainty regarding the general conditions to implement and reimburse pharmaceutical services, makes it necessary to discuss the possible framework itself as this influences the financial implications for the SHI.

As the previous discussion showed, it is unlikely that a remuneration rate of ≥ € 50 per MR would be considered based on the BIA model developed here. The ABDA contemplated € 1 per minute as a basis of assessment and thus, a review of 60 minutes would amount to a remuneration rate of € 60 (Richling & Rose, 2017). However, the proposed remuneration rate of € 60 aims to be cost-covering but does

not include a profit margin which would make MRs a stable source of revenue (Müller-Bohn, 2016). Therefore, it seems necessary to consider other financial means aiming to overcome the discrepancies between the needs and wishes of pharmacies and the financial feasibility of the SHI.

One possible solution to overcome this gap could be to simply restrict the service of MRs to a few and therefore to reduce the quantity of MRs being performed. Examples could be the increase of the eligibility age or defining polypharmacy stricter (e.g., more than 7 pharmaceuticals) as mentioned by E2. Similar restrictions are also implemented in other international pharmacy clinical care services (Houle et al., 2014). In addition, the approach to tighten the eligibility is in line with the current political situation as clarified in section 129 subsection 5e SGB V

> *The relevant umbrella organization of pharmacists formed to represent the economic interests shall agree with the National Association of Health Insurance Funds in consultation with the Association of Private Health Insurance Funds on the pharmaceutical services pursuant to sentences 1 to 3 as well as on the details of the respective conditions of entitlement, on the remuneration of the services rendered and on their settlement.*

Accordingly, it would be possible to restrict this service to a well-defined audience. Nevertheless, whatever restriction will be chosen, it is likely that the entitled patient group will increase in the future. For this reason, despite a restriction, high financial consequences can still be expected in the future.

The experts mentioned some sort of pre-check to identify eligible people with the use of electronic solutions such as the EHR or the electronic prescription. With such a pre-check the SHI would prevent disproportionate MRs and services without indication. However, this requires the EHR and electronic prescription to be widely implemented. This is currently not the case, and it is not known when and how the digital ambitions will be reached in the future as the roll-out for the electronic prescription has been postponed indefinitely in February 2022 (Deutscher Bundestag Parlamentsnachrichten, 2022) and the EHR is not widely used (Paulsen & Schenk, 2021).

Further, it must be noticed that the use of an EHR and providing additional information like self-medication is voluntary. This could lead to a non-identification

of people who might benefit from MRs. If a pre-identification of eligibility is considered as a requirement, this could possibly lead to health care disparities between people using and not using EHR and thus, it may not comply with section 129 subsection 5e SGB V, as the patients are generally eligible to receive MRs. Additionally, making this the sole possibility for pharmacists to perform MRs, contradicts the ambition of VOASG to strengthen the role of pharmacists and to enable them to identify appropriate services for their patients (Müller-Bohn, 2021).

To add a new perspective, reimbursement is not only necessary in order to be able to invest in facilities and equipment but also an appreciation for work. On the other side, section 12 SGB V– the efficiency principle – clarifies that services must be "*sufficient, appropriate and economical*" and are not allowed to "*exceed what is necessary*".

As a result, there may be a significant difference between cost-effectiveness according to the efficiency principle and, from the perspective of pharmacists, appropriate remuneration. An action to overcome this disparity could be additional co-payments by patients for every MR performed. Currently, patients are paying out-of-pocket to receive MRs and apparently there is willingness to do so. However, there are no studies conducted which aim to identify patient groups taking advantage of this service and whether there are socioeconomic differences in the utilisation. Without this knowledge, it is not known who is currently in use of this pharmaceutical service.

It is imaginable that a co-payment could lead to similar results like the so-called *medical practice fee* (Praxisgebühr). Between 2004 and 2012, people insured in the SHI had to pay at least € 10 quarterly when visiting the physician or other health care providers. The aim was to strengthen the personal responsibility for one's own health, to reduce self-referrals and to have short-term financial relief for the SHI (Linnekugel, 2012). However, results showed that patients with poorer health and patients in a lower-income situation went less often to the physician which often caused a worsening of their health status (Bertelsmann Stiftung, 2005). Because of not reaching the goals and rather worsening the health situation for people in need, the medical practice fee was abolished in 2013 (Bundesministerium für Gesundheit, 2012).

A lower socioeconomic status is often associated with poorer health (Agardh et al., 2011). Therefore, it can be assumed that many people eligible for MRs could have a socioeconomic disadvantage. Consequently, it is possible that both the current out-of-pocket payment and a possible co-payment contribute to differences in the equity to access this health service and could exacerbate a disparity in health care.

6.2 Findings of the Expert Interviews

When talking about the requirements to reimburse MRs, it could be established that both the implementation and reimbursement of MRs split into two stages. Further, it has been noticed that the requirements for the reimbursement are similar to experienced barriers in the pharmacy as mentioned in 3.2.2.

As clarified by E1, the starting phase should be used to mainly gather knowledge and data. So, in the beginning, only documentation is necessary – preferably with some sort of additional education. Documentation has been identified as a key aspect for the remuneration of this pharmaceutical service in other countries as well. Exemplary, British Columbia, requires documentation of the medication history including a patient section and a health care professional section to identify all the relevant medications. Further, when a drug therapy problem has been identified or an action has been taken by the pharmacist, a special documentation form has to be filled out as well (The Government of British Columbia, 2022).

The importance of educational training has been highlighted by the recent consolidation between Apo-AMTS and ATHINA (Deutsche Apotheker Zeitung, 2022). By consolidating, they aim to provide a more efficient training concept without regional distinctions (Deutsche Apotheker Zeitung, 2022). With this development and the future nationwide launch of equal preparatory training, it should be contemplated to require a certificate as proof for the participation in a training to be able to claim reimbursement for the provision of MRs.

In the long term, the use of knowledge databases and digitalised documentation tools and further the presence of appropriate equipment and facilities including well-trained employees should be ensured.

An example for a knowledge base and digitalized documentation could be the use of CDSS. One such example is the medication management software

Medinspector® by the Viandar GmbH (Viandar GmbH, 2022) which is also part of a digital pilot study by the GWQ ServicePlus AG (Middendorf-Piniek, 2021). The aim of this medication management software is to improve MTS by providing a communication platform where pharmacological intervention suggestions can be transmitted digitally and adopted after review by the physician (Viandar GmbH, 2022). A medication management software provides the opportunity to increase the scalability and standardisation of processes and could be used to gather data regarding the presence of DRP for different subgroups. Accordingly, the use of a medication management software should be considered as a requirement for the reimbursement of MRs in community-pharmacies.

As mentioned by E2 it is necessary to ensure the presence of well-trained employees who can perform MRs in large scalability. This requirement is in accordance with the literature on the requirements for the implementation of MRs in community-pharmacies. As clarified by Schulz (2017) this does not only include the presence of well-trained employees but also workflows which enable the undisturbed performance of MRs in free periods and in separated areas of the pharmacy. He proposes that MRs could be performed on fixed days when good work staffing is guaranteed.

In this context, it could be considered to require some sort of “office hours” comparable to the consultation hours of physicians (Kassenärztliche Bundesvereinigung, 2020). This requirement could also serve as a regulation for the implementation of MRs. For example, it could be imagined that the reimbursement is at least partly based on the opening hours meaning that a pharmacy with more “office hours” where MRs can be conducted receive a greater financial reimbursement compared to pharmacies who do not provide fixed times for the performance of MRs.

6.2.1 Perception of the Role of Pharmacists

Even if the mentioned requirements have been implemented in a community-pharmacy, there are additional challenges. Considering the demographic shift and increasing prevalence of multimorbidity, it is necessary to optimise the medication treatment of people efficiently. Given the decline in the number of physicians in rural

areas, optimal treatment of patients is a challenge now and in the future (Bundesministerium für Gesundheit, 2016b).

Accordingly, it is advantageous for pharmacists to receive more competencies with the VOASG and to be able to make a higher contribution to health care by shifting to a more patient-oriented approach. Although policy efforts have been made to strengthen the field of activity of pharmacists, especially with regards to medication management, the results of the expert interviews show that there is still a perception that pharmacists are an inappropriate professional group to perform MRs.

Similar reservations have been discussed in other studies as well. A qualitative analysis of 18 pharmacists, physicians, and experts from the SHI showed that pharmacists are often perceived in their traditional role as a salesman (Al-Kaddah, 2020). In addition, some patients do not fully trust the pharmacist to perform MRs as they think that the pharmacist is not qualified enough to do so (Uhl et al., 2018). On the other side, results from the ARMIN project indicate that patients gained benefits from the collaboration of physicians and pharmacists, were more confident with their medication and showed an increased feeling of safety after participating in the project (Eickhoff et al., 2022). One study showed that physicians prefer to start a MR by themselves but are fond of a collaboration with pharmacists later on (Rose et al., 2019). As identified by Löffler et al. (2017), there are three barriers promoting the lack of collaboration, namely a lack of mutual trust and appreciation, insufficient communication structures and disagreement regarding the importance of pharmaceutical information.

Therefore, as a foundation to implement and offer MRs, it is necessary to improve the collaboration between physicians and pharmacists by overcoming the identified barriers and strengthening the perception towards the role of pharmacists. In some Canadian studies, the challenge of communication between pharmacists and prescribers has been addressed and suggestions have been proposed. One suggestion included a creation of new fee codes or the modification of existing fee codes for the physicians which refer to MRs and for example the additional consultation with pharmacists (Harris & Argáez, 2021). In addition, a performance-based model providing additional compensation based on important outcomes like the reduction of unnecessary medications has been suggested which could function as an incentive to communicate with physicians (Harris & Argáez, 2021).

Another concern raised regarding the eligibility of pharmacists to perform MRs is that patients do not necessarily need to go to a certain pharmacy. This causes a lack of overview of OTC medications for example and could lead to additional performance of services. However, in a survey conducted by Forsa, 88% of 13.000 respondents indicated that they mostly buy their medication in one pharmacy (Pharmazeutische Zeitung, 2015). Therefore, it is questionable whether his challenge should be of great concern.

Nevertheless, it is relevant for pharmacies to strengthen customer loyalty. One action in this regard is a customer card which offers for example discounts for OTC medications (Freund, n.d.). Furthermore, it provides the opportunity to improve MTS if all the pharmaceuticals are bought with the use of the customer card in one pharmacy. This would not only lead to a comprehensive overview of prescribed medications but also of OTC medications (Apotheke Adhoc, 2016). Subsequently, it can be assumed that, when used in the right way, customer cards could be a great opportunity to improve MTS.

But even when considering the use of customer cards and the awareness of every medication in use, the pharmacist often does not have the full overview of the health status including diagnosis and laboratory data – at least not in simple and intermediate MR. Therefore, again the need to promote collaboration between physicians and pharmacists is necessary and the structured communication as, for example, supported by the CDSS needs to be considered.

6.3 Proposal of Health Economic Model

Higher costs for MRs can be legitimized if benefits can be measured. For this, a detailed study is necessary that models the cost-effectiveness evidence. As a CEA is not part of this elaboration but has an influence on the financial implications for the SHI, it seems appropriate to shortly discuss assumptions and recommendations for the CEA.

The CEA should be based on a HEM which has been developed in accordance with the key instructions on health economic modelling (European Network for Health Technology Assessment, 2015). To identify the patient groups benefiting from MRs, data should be collected with, for example, the discussed digitalisation tools and

customer cards. It is necessary to perform a long-term evaluation as it is possible that there is a long-term effect of MRs, for example because of a possible prevention of comorbidities because of a better therapy adherence. Therefore, it should be considered to apply a Markov-model as it is suitable to illustrate chronic conditions like T2D and as it provides the opportunity to include the long-term impact.

Ideally, a RCT is being conducted to measure the outcome of MRs. Further, as discussed in the expert interviews, patient-related outcomes such as patient satisfaction or QoL should be included and measured using standardised questionnaires (e.g., EQ-5D). For T2D, parameters like HbA1c and blood are often included in publications (Al-Babtain et al., 2021b) and should also be used in future research.

With regards to the financial implications for the SHI, it is necessary to find out when cost-effectiveness is reached. For this the costs should be described, like in the BIA, in an annual way. To be consistent with the literature and the present BIA, it is recommended to include the main expenditure positions being hospitalisation, outpatient-treatment, and pharmaceutical supply. Further, the implementation and utilisation rate need to be assessed, as this influences the expenditure for this service and, possibly, the allocation to other services.

In this matter, the utilisation rate should be analysed for different demographic regions, provinces, and socioeconomic groups to be able to identify health disparities and implement regulations if necessary.

6.4 Strengths and Limitations

The strength of this elaboration is particularly evident in the implementation of a BIA which considers the existing data situation. According to the current state of knowledge, no BIA has been carried out for community-pharmacy based MRs – neither in Germany nor globally. Since analysing the cost-effectiveness has not been possible at this stage, the BIA allowed to estimate at least a rough direction of the financial implications of introducing MRs for people with T2D.

An additional strength is the focus on the perspective of the SHI towards this topic. Many studies and expert interviews conducted aimed to analyse the perception of either pharmacists or patients towards the implementation of community-based

MRs. The perception of the funding institution towards requirements for the reimbursement of such services has barely been discussed. In this context, it was an advantage that both experts have different professional backgrounds which could explain different perceptions on some aspects.

Further, it is a plus that the results of this study were integrated in both the current international research and national political debate. This provides a comprehensive view on the topic of pharmaceutical services and its challenges.

6.4.1 Limitations of the Business Impact Analysis

There are several limitations to the BIA model, starting with the nature of a BIA. A BIA is based on various assumptions which can be explained and underlaid with data. However, it still consists of uncertain aspects and is based on the perspective and the considerations of the researcher which may influence the results and validity. To increase the validity of this analysis and to minimise uncertainties and biases, the BIA has been developed using the recommendations of a guideline for good practice by ISPOR. Nevertheless, there might be different assumptions and considerations made regarding the variables used here leading to different results. Because of the non-existent of comparable studies and publications performed on this topic, a comparison and integration into the current research has not been possible and it remains unclear if other BIA would lead to similar or completely different results.

Another limitation is the data situation regarding T2D. There are fluctuations in the figures for expenditures and a precise breakdown into subgroups was not possible, as there was hardly any data showing the use of resources broken down by subgroups (e.g., DMP participants or applied medication therapy). Since it can be assumed that there are differences in the use of MRs in the subgroups, the model would have been even more accurate when it examines which patient groups within T2D incur which costs.

Also, it was focused on community-pharmacies. Possible influences of online pharmacies on community pharmacies or buying-behaviour of customers were not taken into account. This is a limitation as it is possible that not every individual buys

their antidiabetic medication in a community-pharmacy and are therefore not identifiable by the community-pharmacist.

Further, the focus of this elaboration was the financial feasibility of the reimbursement of MRs from the perspective of the SHI. Therefore, expenditures of the SHI were of interest and not expenditures or financial consequences for the community-pharmacies. It is expected that the implementation of MRs would lead to additional costs for community-pharmacies concerning amongst other things the salary of employees or the investment in additional equipment. These considerations have not been included in the model but may impact the results. For example, it has not been analysed whether the supposed patient group and accordingly number of MRs could be performed in community-pharmacies in general. As soon as there is more experience with conducting MRs, a second BIA should be performed including this consideration for a tighter definition of the patient group and influence on resources.

To evaluate an intervention, it is often advised to perform CEA and a BIA in health economic guidelines. Because of the mentioned lack of substantial evidence-based benefits, a CEA was not performed. This is not a limitation to the BIA itself as a CEA is not part of a BIA, but it is a limitation to the answering of the research question. For the BIA, it would be necessary to know how resources are being influenced through the impact or benefits generated. As this has not been known at the time of this study, the costs for MRs are treated as additional. However, MRs may cause a decrease in, for example, ADE or hospitalisation which would subsequently lead to expenditure savings in other health care sectors. Then, the model design would be completely different, and the implementation of MRs is not considered solely to cause costs but also to save them. Consequently, the financial implications for the SHI would be different.

6.4.2 Limitations of the Expert Interviews

There are several limitations to the methodology of expert interviews. For a start, the information received from the interview depends highly on the expert's knowledge and perception. The expert interview is not objective and accordingly, the information may be flawed. Therefore, the validity of the results of an expert

interview depends on the quality of experts and reliability is not necessarily given (Dorussen et al., 2005).

As only two experts have been interviewed it is likely that there are more opinions and perceptions on the remuneration of MRs in community-pharmacies which have not been identified and discussed here. Nonetheless, as both experts had different opinions in many areas, this elaboration provided a good insight into the discussion regarding MRs.

Further, the analysis of an expert interview is highly based on the own perception and understanding of what has been said by the experts (Liebold & Trinczek, 2009). Accordingly, misunderstandings can occur which lead to an incorrect conclusion.

6.5 Implications for Future Research

The results indicate that it is necessary to strengthen the knowledge of the impact of MRs. This is crucial for the remuneration of MRs and with that for the comprehensive implementation of MRs in community-pharmacies. Future research needs to identify eligible population groups and collect evidence on the impact of MRs on various outcomes including patient-related outcomes, medical outcomes but also economic outcomes.

Furthermore, as soon as evidence is available, it is needed to provide a more comprehensive economic analysis which includes a CEA. This CEA should consider the assumptions provided in 6.3.

Future research should analyse the impact of online-pharmacies towards the buying-behaviour of individuals and its consequences for the role of community-pharmacies. This is needed as online-pharmacies may influence the possible identification of patient groups in pharmacies and therefore, the financial consequences.

6.6 Implications for Future Practice

After integrating the results of this study into the current political debate, the need for further shaping of the framework conditions to reimburse pharmaceutical

services and particularly MRs has become clearly visible and needs to be addressed by political associations including the DAV and GKV-SV.

The implications for pharmacies include the need to gather data on performed MRs to be able to provide results on evidence on patient related outcomes, savings, and benefits. Therefore, it is necessary to frequently conduct MRs and to prepare the pharmacy for this additional task.

For the SHI it is advised to further pursue the digital ambitions like EHR and electronic prescription to be able to gain benefits. Further, it would be advised to realise more projects with pharmacies, where both the SHI and pharmacies are able to learn from MRs and collect data which can be analysed to understand the impact of MRs.

7 Conclusion

The aim of this elaboration was to estimate the financial feasibility of reimbursing medication reviews for people with T2D and to propose requirements for the reimbursement. For the methodology, a business impact analysis has been performed and expert interviews with representatives from social health insurance funds have been conducted.

To answer first research question, the results indicate that the remuneration of medication reviews for people with T2D can be feasible in certain scenarios and under certain assumptions but showed as well that there might be discrepancies between an adequate and feasible remuneration. But the challenge of lack of evidence-based benefits with regards to the estimation of financial implications has been discussed and the need for future cost-effectiveness analyses conducted in Germany needs to be stressed and considered and targeted in future research.

With regards to the second research question, requirements for the remuneration were identified and include educational training, documentation, digitalisation, and suitable equipment. However, there is need for additional information on the general conditions for the implementation and remuneration of pharmaceutical services.

For an efficient health system despite a demographic change and increasing prevalence of chronic conditions, the absolute necessity to strengthen the role of

pharmacists by changing the perception towards pharmacists and appreciating their skills and knowledge has been emphasised.

The results provided in this study should be considered in the political debate regarding the remuneration of pharmaceutical services and particularly medication reviews.

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Annex

Einwilligungserklärung Interview

Ich erkläre hiermit mein Einverständnis zur Nutzung der personenbezogenen Daten, die im Rahmen des folgenden Gesprächs erhoben wurden:

- *08.02.2022*
- *Julia Klein*
- *Experteninterview zur Masterarbeit mit dem Titel "**Paying for Community Pharmacy-Based Medlcatlon Reviews for Type 2 Diabetes: A Feasibility and Budget Impact Analysis**"*
- *Hochschule für angewandte Wissenschaften, Hamburg*

Die Daten werden im Rahmen eines mündlichen Gesprächs über die Online-Plattform MS Teams erhoben, das mit einem Aufnahmegerät aufgezeichnet wurde. Zum Zwecke der Datenanalyse werden die mündlich erhobenen Daten verschriftlicht (Transkription), wobei die Daten anonymisiert werden. Eine Identifizierung der interviewten Person ist somit ausgeschlossen.

Kontaktdaten, die eine Identifizierung der interviewten Person zu einem späteren Zeitpunkt ermöglichen würden, werden aus Dokumentationsgründen in einem separaten Schriftstück lediglich den Gutachter*innen der wissenschaftlichen Ausarbeitung zur Verfügung gestellt. Nach dem Abschluss des Projekts werden diese Daten gelöscht.

Der Speicherung der personenbezogenen Daten zu Dokumentationszwecken kann durch die interviewte Person jederzeit widersprochen werden. Die Teilnahme an dem Gespräch erfolgt freiwillig. Das Gespräch kann zu jedem Zeitpunkt abgebrochen werden. Das Einverständnis zur Aufzeichnung und Weiterverwendung der Daten kann jederzeit widerrufen werden.

[redacted]
Vorname und Name in Druckbuchstaben

[redacted]
Unterschrift

[redacted]
Datum, Ort

Einwilligungserklärung Interview

Ich erkläre hiermit mein Einverständnis zur Nutzung der personenbezogenen Daten, die im Rahmen des folgenden Gesprächs erhoben wurden:

- *17.02.2022*
- *Julia Klein*
- *Experteninterview zur Masterarbeit mit dem Titel "**Paying for Community Pharmacy-Based Medlcatlon Reviews for Type 2 Diabetes: A Feasibility and Budget Impact Analysis**"*
- *Hochschule für angewandte Wissenschaften, Hamburg*

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Vorname und Name in Druckbuchstaben

[redacted]

Unterschrift

[redacted]

Datum, Ort

Interview 1 / E1

Welchen Stellenwert können Medikationsanalysen in der Gesundheitsversorgungin der Zukunft haben?

Grundsätzlich kann man schon sagen, dass es einen positiven Effekt haben könnte. Das ist, Sie merken schon, sehr vorsichtig formuliert. Bedeutet auch für uns die Fragestellung: Wie setze ich Medikationsanalysen so um, dass sie den größtmöglichen Nutzen entfalten? Das heißt also, was sicherlich die Herausforderung dabei ist, diese Patientengruppe eindeutig zu identifizieren, die davon profitieren können. Was auch eine Herausforderung ist, ist die Medikationsanalyse so aufzugreifen, dass wirklich einpositiver Effekt entsteht. Es ist eine komplexe Intervention, wenn ich aus der Versorgungsforschung daraufschaue, die sehr schwer nach Kausalitäten aufzuschlüsseln ist. Und dann, was sicherlich auch eine Herausforderung ist, der nächste Schritt: die richtigen Patienten in das richtige Programm zu holen. Idealerweise sollte auch wirklich messbar gemacht werden, was der positive Effekt einer Medikationsanalyse war. Die evidenzbasierte Pharmazie gilt auch für Dienstleistungen, für kognitive Services. Das heißt, wir müssen uns die Frage stellen: Sind Maßnahmen, auch wenn sie komplex sind und teilweise schwer in der Realität zu differenzieren, so abbildbar, dass wir davon ausgehen können, dass ein positiver Impact entsteht, in welche Richtung auch immer? Das kann die Lebensqualität sein. Das ist sicherlich aber auch der monetäre Effekt. Haben wir eine positive Kosten- Nutzen Relation? Nur dann macht es Sinn, solche Leistungen anzubieten. Nicht nur meines Erachtens aus dem Blick einer Krankenkasse, sondern auch aus dem Blick eines Versicherten heraus. Auch jetzt bieten Apotheken teilweise Dienstleistungen an und lassen es sich privat als Selbstzahlerleistung honorieren.

Auch da muss der Versicherte sich die Frage stellen: Ist es wirklich ein positiver Effekt, den ich damit realisieren kann? Nützt es mir in meiner Gesundheitsversorgung? Kann ich davon ausgehen, dass ich einen echten Nutzen entfalte oder auch nicht? Von daher ist das schon eine breite Fragestellung.

Würden Sie eine Vergütung von Medikationsanalysen pauschal für alle Versicherten der GKVanbieten bzw. für welche Zielgruppen würden Sie das anbieten? Und hierzu auch, würden Sie zwischen der ländlichen und städtischen Versorgung unterscheiden?

Ich würde weniger stark in demographischen Populationen denken, sondern eher schon Populationen, die einen inhaltlichen pharmazeutischen Aspekt haben. Multimorbide Patienten sind ein klassisches Beispiel.Damit haben wir uns auch öfter auseinandergesetzt.

Lässt sich bei den multimorbiden Patienten, die auch eine Multimedikation erhalten durch eine Medikationsanalyse die Arzneimitteltherapie optimieren? Das wäre eine klassische Fragestellung. Man muss sich aber sicherlich auch die Frage stellen, gibt es spezifische Arzneimittel, die besonders „sensibel“ sind, also wo eine hohe Einnahmetreue einerseits notwendig ist, die aber auch hoch potent sind, zum Beispiel die moderneren Krebsmedikamente, die man einnimmt, also orale Krebsmedikamente. Das ist im Wesentlichen finde ich immer noch aus der Literatur heraus eine hypothetische Frage, weil es Hinweise gibt, dass man einen positiven Effekt irgendwie erreichen kann, dieser sich aber in der Versorgungsforschung sehr schwer finden lässt. Den evidenzbasierten Beleg, welche Intervention zu welchem positiven Nutzen führt, wäre da gut und ein Ansatzpunkt, um solche Leistungen auch sinnvoll anzubieten. Und da ist man meines Erachtens, noch einbisschen von entfernt, ganz klar zu haben was sind denn die Populationen, die wirklich am meisten davonprofitieren können? Bauchgefühl ist multimorbide Patienten, die mehrere Medikamente bekommen. Das könnte ein Ansatzpunkt sein. Wer zusätzlich? Da lässt sich viel hypothetisch generieren. Aber es sollte natürlich schon auf einer gewissen, zumindest guten Einschätzung beruhen, dass es wirklich zu einem positiven Nutzen kommen kann.

Also das bedeutet auch, dass Sie zwischen der ländlichen und städtischen Versorgung nichtunterscheiden würden?

Nein, mir würde da kein Grund einfallen, warum der Ältere in der Stadt mit vielen Medikamenten andere Angebote erhalten sollte als auf dem Land. Da stellt sich für mich eher die Frage: Wie findet man die Zugangswege zu diesen Angeboten? Das heißt also im ländlichen Raum, wo vielleicht Anbieter seltener sind für solche Dienstleistungen, generell Dienstleistungen und nicht speziell Medikationsanalysen, was muss ich da für ein Angebot schaffen, dass ich mit diesen Dienstleistern in Kontakt treten kann? Muss ich 20 Kilometer fahren? Gibt es andere Kontaktwege – Videokonferenzen vielleicht? Wird das von den Versicherten angenommen? Gibt es Hybrid-Modelle zwischen analogem, also persönlichem Kontakt, digitalem Kontakt, einer App? Die Frage würde ich mir da eher stellen, einfach aufgrund der strukturellen Unterschiede zwischen Stadt und ländlichem Raum.

Welche Voraussetzungen muss eine Apotheke Ihrer Meinung nach erfüllen, um die Medikationsanalyse anzubieten und auch vergütet zu bekommen?

Idealerweise fängt das bei der Prozess- und Strukturqualität an. Es gibt auch jetzt im pharmazeutischen Beispiel einige Programme, die dies aufgreifen. Schulungen für

Medikationsanalysen für Apotheker - Athina ist so ein Beispiel. Es ist schon sinnvoll, dass idealerweise nochmal eine Hinführung zu dem konkreten Umgang mit Medikationsanalysen geschieht. Das muss vielleicht nicht alles am Anfang vorhanden sein, aber der Weg sollte dahin gehen, dass man auch das entsprechende Know- How aufgefrischt hat und sich in den Prozessen und Strukturen der Analyse auskennt. Dies kann man auch modular aufbauen. Dazu gehört auch die Ausstattung einer Apotheke. Einerseits muss man Personal haben, die in der Lage sind, so was in einer sinnvollen Skalierung abzubilden. Natürlich kann auch eine kleine Apotheke mit einem Apotheker, so etwas übernehmen. Das halte ich, vielleicht nicht für so erfolgversprechend, wenn nur alle vier Wochen ein Patient von dem Apotheker Feedback zu seiner Medikation erhält. Sondern da wäre schon zu wünschen, dass das wirklich eine Skalierung erhält, wo es umsetzbar und damit auch ein wirtschaftlich umsetzbarer Prozess für eine Apotheke wird.

Natürlich muss es irgendwo einen Maßstab geben, dass jeder Apotheker zu einer Medikation beratenkönnen müssen, ganz unabhängig von der Medikationsanalyse. Das steht in der Apothekenbetriebsordnung. Jeder Apotheker muss tätig werden, wenn er etwas entdeckt, was nicht in Ordnung sein könnte. Wenn er einen Verdacht hat, dass es die falsche Medikation ist, falsche Dosierung, falsches Medikament, falscher Patient, muss er tätig werden, das ist keine zusätzliche pharmazeutische Dienstleistung. Dieser Grundauftrag bleibt auf jeden Fall bestehen, was auch Teil der Vergütung ist, um diese pharmazeutische Beratung sicherzustellen. Wenn man in einen strukturierten und skalierbaren Prozess kommt, da würde ich prozessual und strukturell höhere Anforderungen setzen. Das z. B. umfangreichere Wissensdatenbanken in der Apotheke vorliegen. Die Maßnahme muss dabei über die Standardanforderungen hinauszugehen, um skalierbare Medikationsanalysen in der Apotheke umzusetzen.

Dazu habe ich dann noch eine Frage. Im ATHINA-Projekt wurde, soweit ich weiß, die Medikationsanalyse mit Hilfe von Excel durchgeführt. Welche Rolle spielt denn die Digitalisierung dabei? Würden Sie die Vergütung auch davon abhängig machen, dass man eine Software benutzt?

Perspektivisch wird es auf jeden Fall einer Digitalisierung bedürfen. Gerade wenn ich in skalierbaren Prozessen denke: Wenn Apotheken ein ausreichend hohes Case Load haben, dann hätte ich Sorge, dass mit einer einfachen Excel-Tabelle einiges durcheinander gehen könnte. Es gibt auch Programme auf dem Markt, die das jetzt schon umfangreich abbilden. Aber ich würde immer zwei Elemente sehen. In der Startphase, um das auch ins Laufen zu bringen, muss eine ausreichende Dokumentationssicherheit vorhanden sein. Das kann

auch mal eine Excel-Tabelle sein. Aber mittelfristig oder vielleicht auch kurzfristiger wird sinnvollerweise digitalisiert. Ich denke nicht, dass wir ohne Digitalisierung auskommen. Auch unsere Erfahrungen mit dem elektronischen Rezept oder der elektronischer Patientenakte zeigen, dass die Versicherten es längst einfordern. Insbesondere die Jüngeren sind gewohnt, ihr Handeln digital zu unterstützen: sei es auf Plattformen einzukaufen, Flugtickets zu buchen etc. Der Informationsaustausch ist digital unterstützt und das wird sich auch nicht ändern. Auch lassen sich durch die Digitalisierung Vorteile generieren. Ein Beispiel: in den Krankenkassendaten findet sich keine Selbstmedikation. Es sind die verschriebenen Medikamente dokumentiert. Wenn der Patient es will, findet er diese in seiner ePA (elektronischen Patientenakte). Hier kann man sich Synergien vorstellen: wenn der Patient die Information zur Selbstmedikation in die elektronische Patientenakte einfügt und gleichzeitig eine Allergie gegen dieses Mittel in der ePA hinterlegt hat, kann eine Warnung erfolgen. Damit könnte dann durchaus ein messbarer Mehrwert für den Patienten realisiert werden

Welche Voraussetzungen müssen bei der GKV / Ihrer Krankenkasse vorliegen, damit Sie die Medikationsanalyse vergüten können? Eine Überlegung ist, dass man wahrscheinlich überprüfen muss, ob tatsächlich diese Person, die diese Medikationsanalyse erhält, ob sie wirklich der Zielgruppe entsprechend ist, was möglicherweise Personal benötigt.

Ich möchte in zwei Szenarien denken. Erstens, wie kann man so etwa zeitnah umsetzen? Da können die Voraussetzungen ein bisschen offener sein, um vielen Apotheken die Möglichkeit zu geben, sich an so einem Konzept beteiligen. In diesem Szenario kann man erst mal lernen und üben, Aspekte zu realisieren, die der Beratung noch sehr ähnlich sind, aber entsprechend schon in Richtung Medikationsanalyse gehen. Ich würde sagen, dass wir in den Anfangsphasen von beiden Seiten her dem erstmal annähern müssen und Erfahrungen sammeln können. Voraussetzung ist natürlich, dass in der Apotheke auch eine gewisse Dokumentation stattfindet. Worauf das zukünftig hinauslaufen wird, hängt davon ab welche Patienten bzw. Patientengruppen wirklich profitieren. Wenn ich jetzt vom Idealzustand in paar Jahren ausgehe, da sollten wir genau wissen welchen Effekt eine Intervention hat. Das sind dann höhere Anforderungen. Dazu gehört, dass dann eine Apotheke, diese Versicherten auch sachgerecht identifizieren kann oder wir Patienten, im Rahmen der datenschutzrechtlichen Möglichkeiten, über solche Angebote informieren können. Das heißt, wenn wir wirklich wüssten, die pharmazeutischen Dienstleistungen bei der Medikation XY führen dazu, dass der Patient weniger im Krankenhaus ist, dann könnte man das auch dem Patienten in seiner ePA zurückspielen. Der Patient entscheidet darüber,

ob er möchte, dass ihm Mehrwert Services angeboten werden. Aufgrund der Datenbasis, die wir aus seinen Verordnungen kennen, könnte er sich für einen solchen Service entscheiden und in seiner ePA automatisiert einen Hinweis zu pharmazeutischer Dienstleistung erhalten.

Das sind Zukunftsszenarien, aber den Weg dahin beschreiten wir schon, solchen Patienten individuell Informationen dann, wenn sie es wollen, unter Nutzung ihrer Daten auch zuspielen zukönnen.

Welchen Nutzen sollten Medikationsanalysen für den Versicherten haben, damit sie durch die GKV vergütet werden kann?

Auch da würde ich die Nutzendefinition erst mal breiter fassen. Diese sollten aber messbar sein und wir sollten auch fragen: wird der Nutzen vom Patienten wahrgenommen? Also das ist ein Mindestkriterium.Wie empfindet der Patient so eine Medikationsanalyse? Hat er das Gefühl (auch wenn er es vielleicht nicht pharmazeutisch, medizinisch beurteilen kann), dass durch diese Maßnahme ein positiver Effekt für ihn erreicht wird? Hat er Vertrauen in die Apotheke? Hat er das Gefühl, dass sachgerecht agiert wird und dass er eine gute Beratungsleistung erhält? Die patientenberichteten Outcomes wie auch die Patientenzufriedenheit sind sicherlich Punkte.

Auch die Lebensqualität ist ein Punkt, der für Versicherte wichtig ist, wo man auch kein abstraktes Konstrukt mehr hat, sondern über einschlägige Fragebögen messbar ist. So lässt sich messen, ob die Lebensqualität z.B. positiv beeinflusst wurde. Auch medizinisch-ökonomischen Outcome sind umfasst. Bedeutet bspw.: hat ein Patient, der eine Beratungsleistung erhält, weniger Asthmaanfälle oder kommt ein Patient mit Diabetes weniger ins Krankenhaus? Um dies zu erreichen können nicht nur die Medikationsanalysen, sondern auch andere Dienstleistungen hilfreich sein. Da haben wir dann zwei Elemente. Der Patienten ist durch einen Asthmaanfall oder eine Krankenhauseinweisungwegen Diabetes in einer Belastungssituation. Er profitiert davon, wenn diese verhindert werden kann. Aber, und da schließt sich dann der Kreis zum Nutzenelement für die Versichertengemeinschaft, werden natürlich auch Kosten gespart. Unnötige Kosten, die dem Patienten auch noch Leid verursachen. Das ist der Loop, der entsprechend dahinter liegt.

Angenommen, man weiß wer von Medikationsanalysen profitiert, was wären Sie bereit für eineMedikationsanalyse zu zahlen und wie würden Sie diese Vergütung ausgestalten? Also gibt es beispielsweise Mindestmengen in der Apotheke, gibt es

vielleicht Maximalmengen, für den Versicherten selbst? Gibt es da schon Überlegungen?

Also noch nicht konkret. Die Frage wer von dem Angebot profitiert ist noch nicht klar. Wir gehen jetzt davon aus, dass es ein kleines Incentive zumindest am Anfang geben sollte. Das wird sicherlich nicht voll kostendeckend sein in der Apotheke, aber muss aus unserer Logik im Einzelfall auch nicht voll kostendeckend sein. Wichtig ist, dass in der Apotheke ein skalierbarer Prozess aufgebaut wird. Also der Ansatzpunkt zu sagen, für jeden Patienten, den der Apotheker betreuen will und wenn es nur einmal im Monat ist, muss er eine volle Kostenerstattung haben, das wird glaube ich nicht funktionieren. Das nützt erst mal nur sehr wenigen Patienten und es lässt sich auch nicht auf eine Skala bringen, dass es wirklich für beide Seiten auf einer Populations-Basis einen guten Erfolg hat. Wenn wir erst mal die Erfahrung haben, was denn der Nutzen ist im Bereich der Lebensqualität, der Patientenzufriedenheit, der Vermeidung von medizinischen Events, also Krankenhauseinweisung oder Asthmaanfällen und vielleicht sogar an Einsparung in unterschiedlichen Kostendimensionen, dann könnte man nochmal überlegen, was so ein Preisschild wäre. Aber das kann man nicht nur auf die Kosten-Nutzen-Rechnung bezogen „was sparen wir ein“ betrachten, sondern muss gleichzeitig die Skalierbarkeit dieser Leistung mitdenken.

Interview E2

Welchen Stellenwert können Medikationsanalysen für die Gesundheitsversorgung in der Zukunft haben?

Das finde ich eine schwierige Frage. Es gibt Beispiele für Medikationsanalysen, jedoch ist nach wie vor die ungeklärte Frage „Wer soll denn das machen?“. Der Arzt weiß nur das, was er verordnet, aber ein multimorbider Patient geht zu mehreren Ärzten, er muss aber nicht in nur eine Apotheke gehen. Also weder der Apotheker noch der Arzt kann für sich reklamieren alles zu überblicken. Die Einzigen, die alles überblicken, sind die Kassen.

Ich habe gerade in den letzten Tagen einen Artikel gelesen, der noch mal sehr in Frage gestellt hat, was es eigentlich bringt, Medikamente im fortgeschrittenen Alter reduzieren zu wollen. Es war ein Artikel, aber die dahinterliegende Publikation war englischsprachig vielleicht aus dem New England Journal. Außerdem haben wir 2012/ 2013, ein Projekt gemacht mit der KV Schleswig-Holstein. Da wir für uns reklamieren, dass wir die Einzigen sind, die alles wissen, haben wir sämtliche Medikation, die ein Patient bekommen hat, die der KV Schleswig-Holstein zuzurechnen ist, aggregiert. Notfall- und Einmalmedikation, Antibiotikum etc. rausgestrichen und nur, die die Dauermedikation genommen haben inkludiert. Das glaube ich auf größer 7 eingekürzt und der KV zur Verfügung gestellt. Die hat das ihren Ärzten gegeben mit der Bitte das auf das notwendige Maß zu reduzieren. Und dafür haben wir etwas bezahlt, ich weiß nicht mehr wie viel. Und das Ergebnis war - das ist jetzt keine Evidenz, sondern meine Erinnerung - von 100 Leuten hat sich bei 20 überhaupt was verändert. Und es hat sich im Schnitt von 7,8 auf 7,25 verringert. Eigentlich ist nichts bei rausgekommen für die Anzahl der betroffenen Patienten. 80 Prozent haben hinterher das erhalten, was sie vorher erhalten haben. Bei den anderen 20% ist es unerheblich, vielleicht wurde mal ein Medikament gestrichen, aber das war es. Also die Frage ist was bringt das? Die ganzen Dinge mit PRISCUS-Liste und Konsorten und alles andere, bringt das wirklich was, solange wir zum Beispiel keine krankheitsübergreifenden Leitlinien haben? Und die Frage ist, wer macht es denn dann? Ich glaube ohne, dass man die Kassen einbindet, kommt man nicht zu einem vernünftigen Bild. Solange wir so arbeiten wie aktuell, hätten wir ein vernünftiges elektronisches Rezept, wäre es überhaupt kein Thema, dann könnte man alles automatisiert machen. Also solange wir so analog in Deutschland sind, brauchen wir uns darüber aus meiner Sicht keine Gedanken zu machen. Wenn wir einen anderen Ansatz finden, ein elektronisches Rezept haben, alles elektronisch verschrieben wird, dann kann man darüber reden, ob man so was macht.

Für welche Zielgruppen würden Sie die Medikationsanalyse anbieten oder würden sie gar keine Unterscheidung machen?

Wir brauchen schon eine Polymedikation, wenn eine Analyse sinnvoll sein soll. Wenn irgendein Medikament eingenommen wird, dann ist es unerheblich, denn dann ist alles andere teurer hinterher. Man braucht Leute, die die Polymedikation nehmen. Und ich würde auch sagen es macht Sinn im höheren Alter, was auch immer jetzt höheres Alter konkret ausmacht. Ich glaube, die PRISCUS-Liste legt 65 Jahre zu Grunde, aber darüber kann man sicherlich streiten. Die Frage ist auch, ob Polymedikation mit 45 so viel anders ist als mit 70. Aber das wäre die beiden Grenzen, die ich erst mal einführen würde. Und wenn man Erfahrung hat, kann man das erweitern. Wenn das elektronische Rezept besteht und man das sinnvoll umsetzt, und dass ist meine große Sorge, dass man das nicht vernünftig umsetzt, aber dann brauche ich dafür nichts zu bezahlen, denn dann kann ich das elektronisch machen und mit der hinterlegten künstlichen Intelligenz die Patienten rausfischen, die kritische Kombinationen haben und könnte die ganz gezielt irgendwohin schicken, wo man dann die Analyse macht. Und dann kann man dafür auch 20 Euro zahlen oder was weiß ich. Je besser ich das kondensieren kann, desto höher ist der Betrag, den ich dafür zahlen könnte.

Eine kurze Nachfrage, die Selbstmedikation ist kein Teil des elektronischen Rezepts, oder?

Ja, das ist diese Brown-Bag Frage. Die ist nicht drin, wobei Selbstmedikation über Rezept erfolgen kann. Man müsste an einer Stelle anbieten, dass man das manuell hinzufügen kann. Wir könnten auch eine sinnvolle EPA haben, wo der Patient das hinterlegen könnte, dann könnte man diese Information da hinzufügen. Auf der anderen Seite ist die Grundannahme, alle Selbstmedikation kann nur OTC sein oder ich nehme die Tablette von einer anderen Person. Das ist aber völlig unkontrolliert. Aber sonst kann es nur OTC sein. Die Grundannahme von OTC ist, dass das nicht schädlich ist, jedenfalls nicht überproportional, dass man es deshalb verantworten kann, dass es OTC ist. Was nicht heißt, dass es da keine Interaktion gibt oder, dass wenn ich in vier Apotheken gehe und mir vier Packungen Paracetamol hole, dann habe ich eben keine 10er Packung.

Was halten Sie von der Überlegung, zwischen der ländlichen und städtischen Versorgung zu unterscheiden, um im ländlichen Raum die Gesundheitsversorgung zu verbessern?

Halte ich zunächst nichts von, weil die primäre Intention nicht ist, die Gesundheitsversorgung zu verbessern durch den Medikationscheck, sondern das individuelle Risiko zu mindern und das ist unabhängig davon, ob ich in Hamburg wohne oder in Mecklenburg-Vorpommern. Und wer glaubt, über eine Medikationsanalyse könne man Geld sparen, der hat das System sowieso nicht verstanden. Wenn ich das aus Sparsamkeitsgründen mache, dann sollte ich lieber gleich die Finger davonlassen. Manchmal wäre nämlich ein sinnvolles Ergebnis einer Analyse, dass man nicht Medikament A, B, C gibt, sondern Medikament X. Leider ist x doppelt so teuer wie A, B, C zusammen, aber diese Option müsste ich offenlassen. Insofern, wer das als Sparkasse betreibt, der wird scheitern. Man muss es medizinisch betrachten, dann kann das Sinn machen. Ob es dann Sinn macht, ist eine andere Frage und man liest immer so viel über Arzneimittelnebenwirkungen und die vielen Krankenhausaufenthalte, verursacht durch die Nebenwirkung. Ich bin mir nicht sicher, wie vertrauenswürdig diese ganzen Statistiken sind, denn das, was das Krankenhaus erlöst, erlöst es, indem es die Diagnosen möglichst gewinnbringend kombiniert, im Sinne von Nebendiagnosen und nicht dem klinischen Verlauf.

Das ist tatsächlich eine Frage, die ich Ihnen stellen wollte. Denken Sie, dass die Medikationsanalyse zu Einsparungen für die GKV in anderen Bereichen führen kann? Eben weil gesagt wird, dass es möglich ist, dass die Hospitalisierung dadurch gesenkt wird oder dass es zu weniger Nebenwirkungen und deswegen zu weniger Arztbesuchen kommt?

Arztbesuche sind relativ uninteressant, weil wir eine Kopfpauschale zahlen. Wir haben eine Analyse gemacht, wo wir Anti-Diabetiker und die Leitlinie angeschaut haben, wo stand stell die auf Metformin und SGL-2. Wir haben kreuz und quer analysiert und kamen zum Ergebnis, dass bei der Verordnung von SGL-2 Medikamenten die Gesamtkosten niedriger waren durch zum Beispiel weniger Krankenhausaufenthalte und Ähnlichem. Da war dann die Frage, was machen wir mit dem Wissen? Das hieße ja, man müsste anfangen, statt € 0,20 am Tag € 2 zu bezahlen, in der Hoffnung, dass sich das auf alle reproduziert. Der Einspareffekt darf nicht im Vordergrund stehen, selbst wenn ich als Kassenvertreter hier sitze, aber ich bin auch Arzt. Damit scheitert man. Man spart nicht so viel ein, dass man von 7,8 auf 7,25 reduziert, dann erspart man sowieso nichts.

In der Masterarbeit fokussiere ich mich auf die Medikationsanalyse, die von der Apotheke durchgeführt werden kann. Welche Voraussetzungen muss eine Apotheke Ihrer Meinung nach erfüllen, um die Medikationsanalyse vergütet zu bekommen?

Also ich hoffe nicht, dass das ausschließlich mein Berufsstand ist, aber ich finde nach wie vor, dass der Apotheker die ungeeignetste Quelle für diese Analyse ist. Denn was macht er mit seinem Wissen hinterher? Verordnen tut es der Arzt. Der Apotheker ist nichts weiter als der Verkäufer, der das Präparat über den Tisch reicht und im günstigen Fall, berät er den Patienten noch, wie er es einnehmen soll und worauf er dabei achten soll. Aber es ist ohne jede Konsequenz. Er müsste es dann wieder an den Arzt zurückspielen und mit dem Arzt diskutieren, ob er das Medikament zukünftig streichen will oder nicht. Mit welchem Arzt diskutiert er das? Wir haben kein Versorgungssystem, wo der Hausarzt so eine Schlüsselposition einnimmt. Finde ich schwierig. Wenn überhaupt irgendwer aus meiner Sicht sinnvoll eine Analyse machen kann, dann ist es der Arzt und wahrscheinlich am ehesten tatsächlich der Hausarzt. Selbst wenn man dem dafür wahrscheinlich noch andere Kompetenzen geben müsste, als er das momentan hat. Aber Apotheke halte ich überhaupt nichts von, weil der eben nur das sieht, was bei ihm über den Tisch geht. Und ich weiß es selbst von mir. Ich besorge nicht alles aus einer Apotheke. Ich hol mir das da, wo ich gerade bin. Und wenn ich weiß, heute brauche ich was und ich komme vorbei, dann hole ich mir das da.

Also würden Sie sagen, eine Apotheke könnte so was nur durchführen, wenn die Interaktion mit dem Arzt auch wirklich gegeben ist, dass da eine enge Verbindung ist? Dann könnte sie den Arzt unterstützen?

Ja, aber ich komme immer auf dieses unvollständige Bild zurück. Nichts ist schlimmer, als Schlüsse aus einem unvollständigen Bild zu ziehen. Und der Apotheker hat definitiv ein unvollständiges Bild. Genauso wie der einzelne Arzt ein unvollständiges Bild hat. Da kommt man schnell zu Fehlschlüssen und mit welchem Arzt spricht denn jetzt der Apotheker dann? Er kennt nur die Ärzte, von dem bei ihnen Rezepte eingelöst worden sind. Und wenn sie sich den Datensatz angucken - doch da steht sogar der Leistungserbringer drin. Also theoretisch könnte sogar der Apotheker den Arzt herausfinden, wer das gemacht hat. Das ist schon richtig, aber macht er sich die Arbeit? Hätte ich Zweifel.

Welche Voraussetzungen müssten denn bei der GKV bzw. bei der Krankenkasse vorliegen, damit die Medikationsanalyse vergütet werden kann? Eine Überlegung war, dass wenn man Medikationsanalysen für bestimmte Subgruppen vergütet, auch

Personal benötigt, die prüft, ob diese Medikationsanalyse notwendig gewesen ist, um Abrechnungsbetrug zu verhindern.

Ja, das sind sicherlich theoretische Überlegungen. Nun ist es vom Datenfluss so, dass wir als Krankenkasse Apothekenabrechnungen mit etwa 30 Tagen Verzug bekommen. Aber dann ist die Leistung erbracht, die Leistung ist abgerechnet und die Leistung ist zumindest abschlagsweise vergütet. Nun ist es kein Problem rückwirkend wieder zurückzurechnen und Geld einzubehalten, wenn man anderer Ansicht ist. Aber sie schafft damit natürlich erhebliche Verwaltungsaufwände, weil das alles gecheckt werden muss. Man braucht vorher eine einheitliche Liste für wen darf so was erbracht werden? Anhand dieser Liste müsste man das checken können, aber nur weil ich über 65 bin und nur weil ich sieben Medikamente nehme, heißt das noch nicht, dass bei mir die Analyse sinnvoll ist. Die Analyse ist nur dann sinnvoll, wenn entweder Medikamente vorliegen, die sich gegenseitig stören. Das eine senkt den Blutdruck, das andere erhöht den Blutdruck. Dann muss ich mich fragen, was da richtig ist oder die für den betroffenen Patienten nachteilig sind, also der Medikation zum Beispiel beim älteren Menschen, die die Sturzneigung erhöht oder ähnliches. Da ist es eine Überlegung, ob man die weglässt, aber viel häufiger ist zu überlegen, ob man die ersetzt durch etwas anderes. Das heißt ich ersetze nur das A durch B, was weniger Sturzneigungen fördert. Für wen trifft es zu? Ist es sinnvoll in dem Fall? Und deshalb braucht man einen Pre-Check. Und das geht eben perfekt über das elektronische Rezept. Ich gucke mir an, was kriegt derjenige. Da alles elektronisch ist, erwische ich auch wirklich alles. Jede Verordnung, die gemacht wird, egal von wem, würde ich erwischen und könnte vorher durch ein intelligentes System prüfen, gibt's Widersprüche in der Verordnung oder Überschneidungen, gibt es besonders nebenwirkungsreiche Medikationen. Man könnte sagen „Hier Herr Müller, Sie betrifft das. Sie erfüllen drei rote Kreuze in ihrer Medikation.“ Und dann könnte das meinetwegen auch der Apotheker sein, der das erbringt, weil das schon alles vorher geprüft ist. Das ist nicht mehr „ich habe heute nichts zu tun, da kommt Frau Müller rein, die ist über 65 und nimmt die Medikamente. Da mach ich jetzt mal Medikationscheck“ sondern das wäre schon vorgeprüft. Hier ist jemand, da gibt es gute Gründe, warum der das braucht, und dann macht er das. Bleibt beim Apotheker immer noch das Problem, dass er es nicht selbst verändern kann.

Welchen Nutzen sollten Medikationsanalysen für den Versicherten haben, damit sie durch die GKV vergütet werden können?

Aus meiner Sicht der einzige Nutzen, den so etwas haben sollte, ist ein individueller Patientennutzen. Dass es ihm hinterher besser geht, weil er weniger Nebenwirkungen hat

oder weil er weniger Komplikationen hat, nicht stürzt, nicht unterzuckert, was ich jetzt nicht als Nebenwirkungen einsortieren würde. Nebenwirkungen wären für mich Kopfschmerzen, Schwindel, Magenschmerzen oder ähnliches. Aber wenn daraus wirklich dann was reduziert, das würde ich nicht mehr unter Nebenwirkungen fassen. Es muss schon patientenrelevant sein. Wie gesagt, einsparen tut man darüber nichts. Wer das macht, um was zu sparen, der übersieht die Kosten, die das verursacht.

Wenn man voraussetzt, dass der individuelle Patientennutzen vorhanden ist, wie würden Sie die Vergütung von Medikationsanalysen denn gestalten, insbesondere in welcher Höhe würden Sie das veranschlagen? Was halten sie für angemessen?

Das hängt glaube ich sehr davon ab, was für ein Zeitaufwand das nachher wirklich verursacht und es muss auch in einer sinnvollen Relation stehen. Wenn Sie sich überlegen, ein niedergelassener Hausarzt hat, glaube ich, etwa ein Budget von € 45 im Quartal für die Versorgung seiner Patienten im Durchschnitt. Dann kann ich nicht € 30 für eine Medikationsanalyse bezahlen. Auf der anderen Seite, wenn ich dafür € 10 bezahl, erhalte ich wahrscheinlich keine Leistung dafür, weil jeder sagt, dafür kann ich drei Minuten arbeiten. Da kann man das jedoch nicht analysieren. Das ist ausgesprochen schwierig. Wäre es nicht GKV, würde ich sagen, dann lasst uns gucken, wie viel der vorher aufgrund seiner Nebenwirkungen an Ressourcen verbraucht hat und wenn wir dann über die nächsten zwei Jahre Einsparungen sehen von 10 Prozent, zahlen wir das. Aber das sind natürlich Überlegungen, die funktionieren in der GKV nicht, da muss ich eine feste Gebührenordnung haben. Also ich denke mal vielleicht € 10 bis € 15 wären adäquat. Aber ich würde es gerne sehr kondensieren auf ein paar Wenige und dann kann man auch darüber hinaus gehen.

Soll es Mindest- und Maximalmengen in der Apotheke geben? Zur Qualitätssicherung könnte es Mindestmengen geben, also, dass eine Mindestanzahl an Medikationsanalysen durchgeführt wird, und was halten Sie von Maximalmengen pro Versicherten, dass z.B. nur ein- oder zweimal im Jahr eine Medikationsanalyse durchgeführt werden kann?

Ein-oder zweimal im Jahr fände ich zu oft. Man kann nicht mit jeder Quartalsverordnung eine Medikationsanalyse machen, es sei denn man automatisiert das. Solange man da händische Arbeit reinsteckt, ist es zu teuer und wenig ertragreich. Wir haben bei allem eine Quotierung in einer Form, beispielhaft die Gestaltung der EBM oder GOÄ, das ist einmal im Behandlungsfall oder im Jahr, also immer ein zeitlicher Kontext. Das braucht man

definitiv. Allerdings, was passiert, wenn jemand in Apotheke A geht und der Apotheker A sagt „Du brauchst eine Medikationsanalyse“ und die macht und drei Tage später diese Person in Apotheke B geht und Apotheker B fragt ihn „Ist bei dir schon mal eine Medikationsanalyse gemacht worden? - Nö, keine Ahnung.“ Und dann macht Apotheker B das und dann sagt ihm die Kasse „Ist aber nicht bezahlt, er war 3 Tage vorher in einer anderen Apotheke“. Mindestmenge ist auch eine Frage. Führt das möglicherweise dazu, dass bei Leuten die Medikationsanalyse gemacht wird, wo man es machen könnte, aber es sinnlos ist, dass man es macht? Obergrenzen auf jeden Fall. Mit Untergrenzen wäre ich sehr zurückhaltend.

Declaration of Independent Work

I hereby declare that I wrote this thesis without any assistance and used only the aids listed.

Any material taken from other works, either as a quote or idea, has been indicated under

'references'.

Hamburg, _____

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