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Patient Orientation in Health Services Research:

The Example of Type 2 Diabetes

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List of abbreviations

BMBF	German Federal Ministry of Education and Research
BMI	Body Mass Index
CI	Confidence Interval
CVD	Cardiovascular Disease
DIAB-CORE	Diabetes Collaborative Research of Epidemiologic Studies
DMP	Disease Management Programme
EQ-5D	Euro-Qol 5 Dimensions (Questionnaire)
HbA1C	Glycosylated Haemoglobin, Type A1C
HDL	High-density Lipoprotein
HR	Hazard Ratio
HRQL	Health-related Quality of Life
ICF	International Classification of Functioning, Disability and Health
IDF	International Diabetes Federation
IOM	Institute of Medicine (US)
KORA	Cooperative Research in the Region of Augsburg
LDL	Low-density Lipoprotein
MCS-12	Mental Component Summary (SF-12 Subscore)
NGT	Normal Glucose Tolerance
OAD	Oral Antidiabetic Medication
OECD	Organisation for Economic Co-operation and Development
PCS-12	Physical Component Summary (SF-12 Subscore)
PRO	Patient-reported Outcomes
PROM	Patient-reported Outcome Measures
QOF	Quality and Outcome Framework (UK)
SD	Standard Deviation
SES	Socio-economic Status
SF-12/36	12/36-Item Short-Form (Questionnaire)
SHIP	Study of Health in Pomerania
T2DM	Type 2 Diabetes Mellitus
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America

Part I Summary

1. Patient Orientation in Health Services Research

1.1 Objectives of Health Services Research

Health services research is the systematic study of the delivery of health care products and services to individuals and the population under conditions of routine care and how this affects access to health care, quality and cost of health care as well as health outcomes (IQWIG 2017; Lohr and Steinwachs 2002).

The target of health services research lies with the health care system, its institutional, professional and organisational structure and the provision of services. Compared with public health, health services research has a similar analytical frame, the patient and population perspective, and shares the overarching goals, namely the prevention of disease, the prolonging of life and the promotion of health. Unlike public health, health services research does not extend to societal action and responsibilities for health and well-being, and is therefore more confined (Dragano et al. 2016; Schrappe and Pfaff 2011).

To improve health care, health services research evaluates the quality and effectiveness of services, interventions or models of care in real-world settings. In a multi-disciplinary tradition, processes of decision-making, practice and organisational culture and the impact of commercial interests and financial resources and incentives are examined (Boyer and Lutfey 2010). Importantly, the complexity of interventions and their implementation into 'active' contexts is addressed (Geraedts et al. 2017; Greenhalgh and Papoutsi 2018; Schrappe and Pfaff 2016).

Baumann et al. (2016) point to value-driven perceptions of quality in health care, embedded in the societal and political discourse on health care needs and the level of care provision that is appropriate and justified. Adopting this view, the applied stance of health services research in Germany, with its aim to inform policy-makers and to promote evidence-based health care provision, bears significant weight. It makes patient orientation of pivotal importance vis-à-vis economic and political interests in shaping health care policy and provision.

1.2   Strengthening Patient Orientation in Health Services Research

Patient-centredness, as one of six proclaimed aims of health care – the others being safety, effectiveness, timeliness, efficiency and equity – were described in a landmark publication by the US Institute of Medicine (IOM) in 2001:

> '…the patient's experience of illness and health care and […] the systems that work […] to meet the individual patients' needs. […] Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions' (IOM 2001, p. 48).

Further attributes of this rather all-encompassing concept originate from an influential publication commissioned by the Picker Institute in 2008, the 'Patient-Centered Care Improvement Guide':

> 'Ultimately, it is about a collective commitment to a set of beliefs about the way patients will be cared for, how family will be treated, how leadership will support staff, and how staff will nurture each other and themselves' (Frampton et al. 2008, p. 20).

Patient-centredness as an aim and concept underlines changes in the understanding of the roles of patients and health care providers towards joint responsibility and collaborative decision-making. It implies power-sharing on behalf of physicians in terms of recognising and empowering patients as 'experts in their own illness' (Mead and Bower 2000), whilst holding on to the professional authority to grant access to health care services and treatments. Greenhalgh conceptualises clinical decision-making as i) attending to evidence-based knowledge; ii) co-constructing a healing or coping narrative with the patient; and iii) using experiential clinical knowledge to gain judgement of the individual situation (Greenhalgh 2013).

On a health system level, patient-centredness calls for ongoing evaluation and quality improvement efforts, including the use of patient-reported outcome measures (PROMs) (Santana and Feeny 2014). The defining feature of patient-reported outcomes (PROs), compared with other types of health outcomes such as laboratory results, is that they are conditions known only to the patients themselves and obtained directly from them (Patrick, Guyatt, and Acquandro 2008). PROs provide standardised measures of health and well-being that are essential to guide health policy-making, i.e. they offer descriptions of disease burden. PROMs represent

outcomes relevant to patients in relation to the effectiveness of a single intervention or treatment. Underlying this definition is evidence about the relative importance of a range of outcomes from the perspective of patients' needs (Schunemann et al. 2019; Yordanov, Dechartres, and Ravaud 2018; Zhang et al. 2017).

PROMs can be broadly classified as i) condition-specific (measuring, for example, the number and severity of symptoms of a specific condition, outcomes of specific procedures) and ii) generic health-related quality of life (HRQL) instruments that assess a broad range of physical and psychosocial domains. Drawing on the Wilson and Cleary model of HRQL and the model underpinning the International Classification of Functioning, Disability and Health (ICF), Valderas and Alonso differentiate between psychometric, econometric and clinimetric PRO instruments measuring i) symptoms, ii) functional status, iii) general health perceptions (e.g. 'how would you rate your overall health'), iv) HRQL and v) other health-related constructs (e.g. satisfaction with health care processes, self-management) (Valderas and Alonso 2008). HRQL can be seen as the most encompassing concept, bundling together the subjective and dynamic perceptions with regard to one's health or disease status (Bakas et al. 2012; Ferrans et al. 2005).

Two developments in the measurement of health outcomes should be mentioned: first, there is the acknowledgement of the impact of management of therapeutic regimes and self-management on HRQL (Bakas et al. 2012). With a view to evaluating the processes of clinical care, the importance of instruments assessing the quality of communication, the degree of patient activation and shared decision-making and the extent of self-management and satisfaction (of both patients and clinicians) have been highlighted (Santana and Feeny 2014). Second, to allow for more individualised measures, particularly in clinical practice and the evaluation of services, more flexible measures (e.g. goal attainment scales) have been developed as well as item banks and strategies for adaptive testing (Rose et al. 2014; Turner-Stokes et al. 2012). Both should guide assessment of HRQL towards a more comprehensive approach, e.g. in intervention research.

PROMs play an increasing role in public reporting and performance measurement, such as in the UK Quality and Outcome Framework (QOF), and in clinical practice (Calvert et al. 2019; Greenhalgh et al. 2018; Porter et al. 2016; Roland and Guthrie

2016; Van Der Wees et al. 2014). This may help towards critically examining the match between therapeutic decisions, patients' health goals, timely access, integrated care pathways and evidence of under- and overutilisation, driven by commercial interests and by health disparities linked to age, gender, ethnicity and socio-economic status (SES) (Boyer and Lutfey 2010; Calvert et al. 2019; Olde Rikkert et al. 2018; Van Der Wees et al. 2014).

As primary or secondary outcomes in research studies, both trial-based and observational, PROMs describe disease burden and are used in evaluations of interventions and services with the aim of informing decisions regarding clinical recommendations, service development and coverage. The GRADE Evidence to Decision frameworks seek to facilitate the assessment of the quality of evidence, i.e. the quality of instruments, and the translation of research evidence to specific clinical contexts (Alonso-Coello et al. 2016). To advance the integration of the quantitative stance of PROMs with evidence on patient experiences from qualitative studies, the Cochrane Qualitative and Implementation Methods group has developed guidance (Harden et al. 2018).

In summary, research to strengthen patient orientation in health services research aims to facilitate improvements in patient-centred care in real-life settings. In this chapter, patient orientation in health services research has been described as movement towards joint responsibility and collaborative decision-making in health care. Health care services are shifting to primarily manage long-term conditions. Health service research should therefore focus on the role of patients' self-management. HRQL detriments attributable to symptom burden and loss of functional status in chronic illness are of particular importance. Against this background, Anderson et al. call for the following research agenda for health service research to improve patient-centred care:

(1) prioritise research into chronic and often progressive illness, with reference to its impact on the global burden of disease;

(2) focus upon patient-reported outcome measures to assist patients and providers in identifying challenges that arise from illness progression and symptom burden;

(3) develop interventions that help patients to gain positive control over aspects of their illness and/or their responses to them and evaluate their effectiveness (Anderson et al. 2015).

Before moving on to address some of these challenges, drawing on PROMs using the example of my own research in diabetes care, I will briefly outline conceptualisations of the co-production of health by patients in the management of chronic illnesses.

1.3 Patient Self-management in Chronic Illness

Chronic diseases are the leading causes of death across OECD countries (OECD 2019). In Germany, 43.8% of people aged 16 years or older were reported in Eurostat's European Health Interview Survey (EHIS-2) in 2018 to be living with a long-standing illness or health problem (Eurostat 2019). The prevalence of multimorbidity, the coexistence of several chronic diseases, is very high in the older population (Fabbri et al. 2015). Hypertension, allergies, arthrosis and diabetes have the highest prevalence among chronic diseases across European countries (Fehr et al. 2017). Chronic diseases account for the majority of health care utilisation and expenditure. They can be characterised by multicausal, non-linear and intertwined symptoms, which create illness burden and affect multiple domains of life (Anderson et al. 2015).

In chronic illness, patient self-management is a daily, interactive and dynamic process, which constitutes living with the illness, supported by family, community and health care professionals (Bodenheimer, Wagner, and Grumbach 2002; Richard and Shea 2011). Corbin and Strauss perceived three dimensions of self-management: medical management, behavioural management (e.g. adapting lifestyles, activating resources) and emotional work (cited by Schulman-Green et al. (2012)). As Hinder and Greenhalgh point out, people spend only a fraction of their time with health professionals (Hinder and Greenhalgh 2012). Social–cultural and material constraints that shape individual choices are often more influential than medical advice, in view of both behavioural and lifestyle changes, but also whether and how recommended treatment regimens are implemented in daily routines (Barry, Greenhalgh, and Fahy 2018).

In the cumulative complexity model, Shippee conceptualises patients' experiences with care and self-management by distinguishing between illness burden (e.g. symptoms, management and limitations through symptoms) and treatment burden (e.g. appointments, monitoring) (Shippee et al. 2012). Both affect patients' capacity to access health care services, to organise support, to perform self-care and self-management tasks and, ultimately, impact upon health outcomes. Chronic illness forces patients to perform 'adaptive work' to develop responses to new illness or treatment-related issues or limitations as they arise, often in an unpredictable manner. Chronic care interventions and services need to go beyond traditional patient education but should activate the patient and increase or facilitate self-care and self-efficacy, even if patients had initially hoped for quick 'medical fixes' to their problems (Anderson et al. 2015; Holman and Lorig 2004; Michie, Miles, and Weinman 2003). This may include reducing treatment burden in patients and carers overwhelmed by chronic care, as captured in the concept of 'minimally disruptive medicine' (Boehmer et al. 2016a,b; Demain et al. 2015).

1.4   Outline of the Summary

In the following, diabetes will serve as an example of a chronic disease and front-line health care problem that requires multiple patient-oriented interventions based on evidence from health services research. This summary appraises the contribution of the accompanying original research publications in two related fields of study: i) the impact of diabetes on HRQL and ii) the quality of diabetes care with focus on patient-reported indicators and self- management. Chapter 2 provides a brief overview of the societal burden and of challenges in the prevention and treatment of type 2 diabetes. Chapter 3 maps the individual disease burden by measuring the impact of diabetes on HRQL, drawing on a series of studies using cross-sectional and longitudinal data from a pooled analysis of population-based survey studies in Germany. Chapter 4 assesses care processes and outcomes with data from population-based cohort studies conducted in the Augsburg region of southern Germany (KORA–Cooperative Research in the Region of Augsburg).The concluding chapter 5 gives an outlook on future perspectives for research in this field of study.

2. Diabetes as a Chronic Disease and Health Care Problem

According to the International Diabetes Federation (IDF), 8.8% of the world population have been diagnosed with type 2 diabetes, in addition to an almost equal number of people with impaired glucose tolerance that precedes the development of the disease (Cefalu et al. 2016). For Germany, data from five population-based regional studies and one nationwide study within the Diabetes Collaborative Research of Epidemiologic Studies (DIAB-CORE), conducted between 1997 and 2006, provided prevalence and incidence estimates of self- reported type 2 diabetes mellitus. Standardised to the German population, these were 8.6% (8.1−9.1%) for the regional studies and 8.2% (7.3−9.2%) for the nationwide survey (Schipf et al. 2012). Incidence rates calculated by drawing on the respective follow-up studies, conducted between 1997 and 2010, were 11.8/1000 person-years (95%CI 10.8−12.9), with a mean follow-up of 2.2−7.1 years (Schipf et al. 2014). The incidence increased with age and was higher in men than in women. Incident type 2 diabetes was strongly associated with anthropometric markers that reflect abdominal obesity (Hartwig et al. 2016).

Regional differences within Germany were shown for both prevalence and incidence, highest in the east and lowest in the south of Germany, indicating a southwest-to-northeast gradient. It was shown that area deprivation plays an important role in increasing the risk of developing diabetes, in addition to the individual SES and independent of risk factors such as sex, age, BMI, physical activity, smoking status and alcohol consumption (Maier et al. 2013; Maier et al. 2014). Comparing data from the northeast (SHIP-TREND) and south of Germany (KORA F4) in adults between 35 and 79 years of age, the age- and sex-standardised prevalence of undiagnosed type 2 diabetes and prediabetes followed the same pattern of regional differences (Tamayo et al. 2014a). Prediabetes rates were estimated to be 43.1% (95% CI 40.9−45.3) in SHIP-TREND and 30.1% (95% CI 28.4−31.7) in KORA F4; rates of unknown diabetes were estimated to be 7.1% (95% CI 5.9−8.2) in SHIP-TREND and 3.9% (95% CI 3.2−4.6) in KORA F4. These regional differences persisted after adjustment for known risk factors such as BMI, physical activity, smoking or limited education. Thus, environmental and setting-based prevention strategies are of equal importance in behaviour-oriented prevention (Roberts et al. 2019; Stöckl et al. 2016).

The high and increasing prevalence and the high incidence of associated complications and comorbid conditions make diabetes a prime case to assess HRQL as a measure of disease burden in chronic diseases. Generic instruments to measure HRQL are most widely used because they allow for comparison within and between populations and people with medical conditions (Bayliss et al. 2017).

Patient-important outcomes in diabetes can be conceptualised as mortality rates and morbidity, leading to detriments in HRQL and functional status (Gandhi et al. 2008).Type 2 diabetes poses a particular risk of decline in physical health, with its relative position similar to that of congestive heart failure or chronic respiratory disease (Sprangers et al. 2000). Health burden in diabetes also stems from a high prevalence of comorbid conditions. A large population-based sample of people with type 2 diabetes in the US showed that 44.1% had one chronic condition in addition to diabetes, 18.4% had two additional conditions and 11.9% had three or more additional chronic conditions, recorded in 2 years after the diabetes diagnosis (Weir et al. 2016). The likelihood of conditions that have a pathophysiological link to diabetes, such as cardio-metabolic risk factors or cardiovascular disease (CVD), is two or three times higher in people with diabetes, according to a German survey study among adults aged 50 years and older (Du et al. 2013). Estimations of the burden of diabetes in patients with coronary heart disease in a population-based study in Augsburg, Germany, showed reduced HRQL (measured with the EQ-5D 0.82 (95% CI 0.80−0.84)) at baseline and increased mortality (HR 1.68 (95% CI 1.17−2.40)) over a period of 4.1 years (Laxy et al. 2015). The magnitude of the adverse HRQL effects has important implications for public health efforts to lower the risk of developing the disease.

Quality improvement in diabetes care over the last 30 years has led to a standardisation of physician-led care and treatment decisions by practice guidelines and evidence-based medicine. A patient-centred treatment approach is endorsed as a central aim by the American Diabetes Association and the European Association for the Study of Diabetes (Inzucchi et al. 2012). Increasingly, clinical guidelines are replaced by complex sets of clinical decision rules, in particular with regard to glycated haemoglobin (HbA1c) levels, e.g. 6.0−6.5% (42−48 mmol/mol); <7.0% (53 mmol/mol); 7.5−8.0% (58−64 mmol/mol), considered as appropriate treatment aims for subgroups of patients, such as considering multimorbidity (Inzucchi et al. 2015). In Germany, disease management programmes (DMPs) focusing on glycaemic

control and multifactorial risk reduction in type 2 diabetes were introduced in 2003 (Stark et al. 2009). Intermediate endpoints that indicate disease progression and thus increased risk in terms of mortality and comorbidity are often used in assessing quality of care and treatment effectiveness in diabetes care.

Diabetes is associated with high health care costs. Ulrich et al. calculated the overall direct medical costs such as outpatient services, hospital care, rehabilitation and medication to be 1.81 (95%CI 1.56–2.11) times higher in people with diabetes (Ulrich et al. 2016). Relative excess costs were particularly high in younger (<50 years) age groups (Kähm et al. 2019). Weir et al. (2016) found an average number of 20.7 physician visits (SD 21) during the 2 years following diabetes diagnosis with a mean of 8.5 (SD6.4) different physicians in a US- based study. A diabetes diagnosis also bears significant monetary costs depending on the coverage of medical services and drugs in the respective health care system, as well as time costs (Claessen et al. 2013; Icks et al. 2013a,b).

At all stages of the disease, treatment is coupled with a substantial number of self-management tasks such as measuring blood glucose, monitoring of feet and weight, medication, regular attendance at check-ups as well as lifestyle changes to adopt healthy eating habits and increase physical activity (Nefs et al. 2012). Diabetes self-management can be effective in improving short-term process measures (patient knowledge, accuracy of self-monitoring of blood glucose, HbA1c and cholesterol screenings and dietary habits) and health outcomes ('intermediate outcomes', i.e. reductions in HbA1c, lipids, blood pressure, medication use and weight gain) (Captieux et al. 2018). Lower health service utilisation and costs during one follow-up year have been shown (for example, by Strawbridge et al. 2017) in beneficiaries receiving self-management training in a large population-based sample in the US. Evidence remains inconclusive on the attributes of effective self-management support (i.e. education, therapeutic relationship), its antecedents (i.e. health literacy, personal capacities and life circumstances) and consequences (i.e. improved outcomes, reduced health service utilisation) (Captieux et al. 2018; Sloan, Padron, and Platt 2009).

In the following summary of my research and the accompanying original research publications, the overarching theme is disease burden and quality of care in diabetes care, with special focus on PRO-based measurements and developments in Germany. This work aims to contribute in a twofold manner: accumulating evidence on differences in the magnitude and impact of the disease burden in relation to diabetes treatment, age and gender as well as longitudinal disease trajectories is highly relevant for health care decision-making in view of different subgroups of patients. Conceptualising PRO-based integrated measurements of quality of care, drawing on population-based data, is needed to inform and monitor the increasing use of such indicators in routine data and health system-triggered performance measurement. With these data, it was possible to focus in particular on care processes in view of self-management, health care utilisation and patient satisfaction and their linkage to health outcomes.

3. Health-related Quality of Life in Diabetes in a Cross-sectional and Longitudinal Perspective

As part of a BMBF (German Federal Ministry of Education and Research)-funded project (DIAB-CORE), data from several regional and one national population-based cohort studies in Germany were pooled to compare population values of HRQL measured with the SF-36/12 in people with and without type 2 diabetes in both cross-sectional and longitudinal perspectives (Schunk et al. 2012a,b; Schunk et al. 2017). The SF-36/12 is a generic instrument to measure HRQL (Ware at al. 1996). It is a profile instrument and yields summary scores for physical and mental health: the physical component summary (PCS) and the mental component summary (MCS). The SF-36/12 was used in the 12-item version, correspondingly calculating the PCS-12 and the MCS-12.

3.1 Health-related Quality of Life Disease Burden

The cross-sectional analysis of five regional and one national studies, conducted between 1997 and 2006, with a pooled sample of n=9579, shows that type 2 diabetes is associated with lower PCS-12 scores by 4.1points, which equals the decline in PCS-12 between people aged 45 years and 65 years (Figure1) (Schunk et al. 2012a,b). Differences between people with and without diabetes in MCS-12 scores were smaller (−2.5 points) and only significant in women. Age is statistically significantly associated with both PCS-12 and MCS-12 scores for subjects with and without type 2 diabetes. As shown in Figure 1, greater age is associated with lower PCS-12 scores, but increased MCS-12 scores. Differences between subjects with and without type 2 diabetes decrease slightly with age, but there is no statistically significant interaction between age and diabetes.
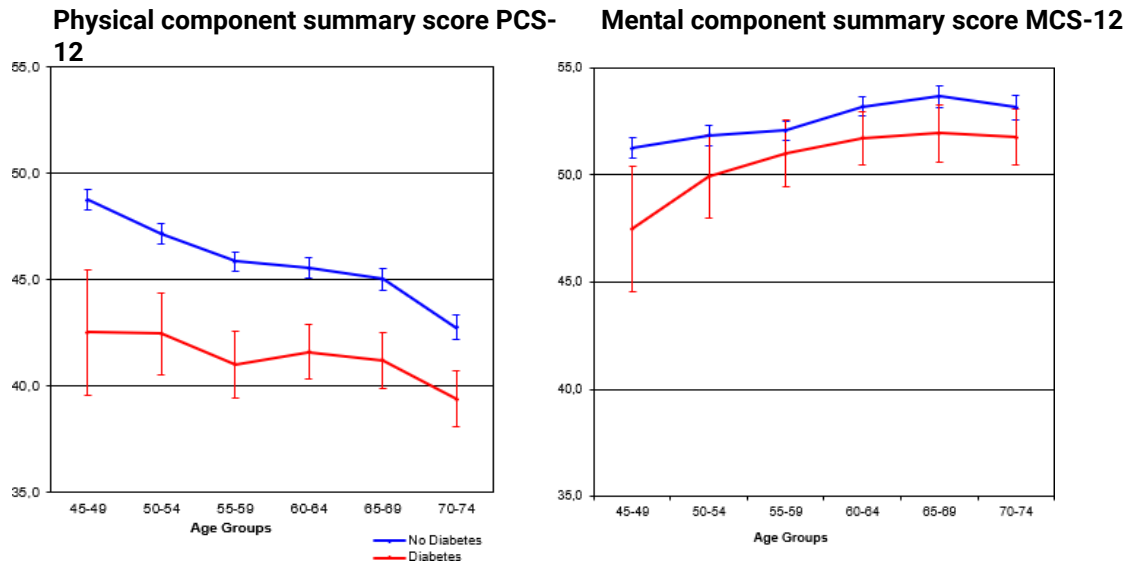
Physical component summary score PCS-12 **Mental component summary score MCS-12**

Figure1: PCS-12 and MCS-12 differences between people with and without diabetes by age group (adjusted for sex and study effects, lines are connected to improve graphical representation) (adapted from Fig 1 in Schunk et al. 2012b)

Further analyses explored the impact of comorbidities, socio-economic variables, obesity and health behaviour on the magnitude of detriment in HRQL in those with diabetes, dividing them according to their treatment with or without insulin. Controlling for age, education, income and health behaviour, the PCS-12 detriment is much more pronounced in people with insulin-treated diabetes (−3.92 (95% CI −5.12; −2.72), compared with people without insulin treatment (−1.88 (95%CI −2.66; −1.10). This is also the case for women with regard to MCS-12 (−3.22 (95%CI −5.53; −0.92) (insulin treated); −1.29 (95%CI −2.78; 0.19n.s.) (non-insulin treated) (Schunk et al. 2012b). Results from former studies were inconsistent as to whether insulin treatment is independently associated with lower HRQL after adjustment for comorbidities. Our results add empirical evidence supporting the view that patients receiving insulin treatment have lower HRQL after adjustment for comorbidities. Myocardial infarction, stroke and hypertension were independently associated with a detriment in PCS-12 and MCS-12. Therefore, we could not show what Hunger et al. (2011) had found with data from the KORA-Age study of 4565 Germans aged 65 years or older, namely the joint impact of diabetes and coronary events on HRQL to be much stronger than their independent effects, indicating the importance of CVD risk factor management in patients with diabetes. However, this may result from the use of a different instrument to assess HRQL, the EQ-5D. The pooled data indicated sex differences, not only regarding insulin treatment and its association with the MCS-12,

but also regarding the association with body weight, as measured by the BMI. These will be addressed in the following.

3.2 Gender Differences and Treatment Effects

When exploring the impact of diabetes on HRQL measured with the SF-12, we consistently found significantly lower PCS-12 scores for both women and men. However, the effects on MCS-12 could only be shown in women. Comparisons of HRQL across different types of diabetes treatment have rarely been undertaken, although treatment types reflect different stages of the disease, differences in the risk of tolerability issues and in the complexity of treatment regimes. By dividing patients with diabetes into subgroups with different treatment regimens (insulin/no insulin), gender differences prevailed. In Figure 2, the pooled summary scores are shown for women and men separately; scores for women are consistently lower than those for men (Schunk et al. 2012b). The diabetes effect on PCS-12 increases for patients of both sexes with insulin therapy. For women only, this can be shown for MCS-12 scores as well. This result was replicated in an analysis of the pooled DIAB-CORE data with a diabetes-only sample (n=846), dividing treatment groups even further (Schunk et al. 2015a). Using subgroups with different treatment regimens (no antidiabetic medication, oral antidiabetic medication (OAD), combination of OAD and insulin, insulin only), women and men have similar PCS-12 mean scores in the no-medication and insulin groups. Men tend to have higher scores than women in the OAD and combination treatment groups, but these differences proved not to be significant. However, with regard to MCS-12 scores, differences between women and men associated with treatment were significant (P-value >0.0001). Compared with men receiving OAD and combination treatment, women had lower MCS-12 scores (49.0 vs. 53.3 for OAD treatment, 47.0 vs. 54.0 for combination treatment). MCS-12 scores exhibit detriments for women in the oral, combination or insulin treatment groups (−4.83 (95% CI −7.57; −3.91); P-value 0.012).

SF-12 Physical Score (PCS-12)

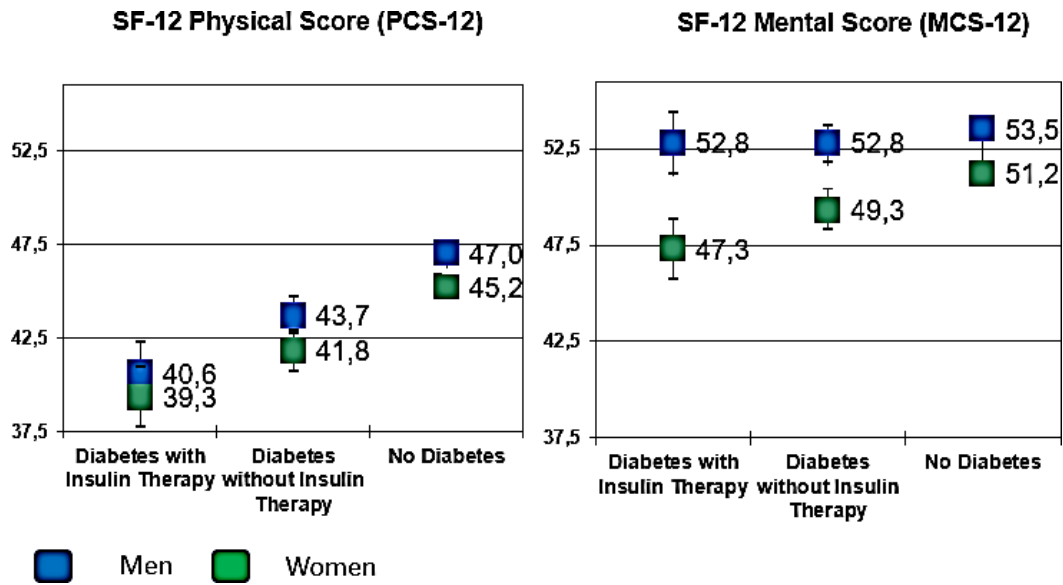**SF-12 Mental Score (MCS-12)**

Men   Women

Figure 2: Differences in HRQL by diabetes status, insulin treatment and gender, adjusted for age and study effects (adapted from Fig 2 in Schunk et al. 2012b)

We also analysed SF-12 single items after dichotomising the item coding (Schunk et al. 2015a). Again, women scored lower than men across all treatment groups involving medication. Differences between women and men were strongest in the OAD and combination treatment groups and reached significance for 5 of the 12 items, such as mental health (feeling downhearted and depressed), social functioning and emotional role limitation (did activities less carefully). One tentative interpretation of the observed differences between women and men is that women may react more strongly with a sense of loss of perceived control, e.g. due to failure of dietary appraisal, when diet- and lifestyle-based treatment has proven to be ineffective and OAD treatment is started as the first-line option. Laxy et al. drew attention to a gender-specific pattern in the impact of weight change on HRQL in the KORA S4/F4 cohort, with a positive association between weight change an MCS-12 in women, mainly driven by questions referring to the domains 'mental health' and 'emotional role limitation' (Laxy et al. 2014a). Overall, there are only a very few studies that describe gender differences in symptom presentation, treatment and control in diabetes patients. More research is needed to clarify the impact of body weight-sensitive chronic illnesses such as diabetes on women to derive gender-specific strategies to improve diabetes management.

3.3   Longitudinal Analysis

Longitudinal analysis of three regional studies and one national study (pooled n=5367) over a mean observation time of 8.7 years pointed to significantly larger declines in mean PCS-12 and MCS-12 scores among people with prevalent and incident diabetes, compared with those without diabetes at both baseline and follow-up (Schunk et al. 2017). Mean score change in PCS-12 per observation year, adjusted for age and study, as shown in Figure 3, is −0.22 (95%CI −0.26; −0.18) points, −0.38 (95%CI −0.50; −0.25) points and −0.53 (95%CI −0.67; −0.39) points for the groups without diabetes, with incident diabetes and prevalent diabetes respectively. For MCS-12, the corresponding numbers are −0.06 (95% CI −0.10; 0.01), −0.18 (95%CI −0.33; −0.04) and −0.43 (95%CI −0.60; −0.27). This indicates a much faster decline in PCS-12 in people with prevalent diabetes (about 5 points over 10 years) compared with a decrease of less than 2 points (for both those without diabetes and, at a lower starting point, those with prevalent diabetes), which we identified in cross-sectional analysis. Unlike in cross-sectional analysis, a decline in MCS-12 over time for both women and men with prevalent diabetes was evident in longitudinal analysis.
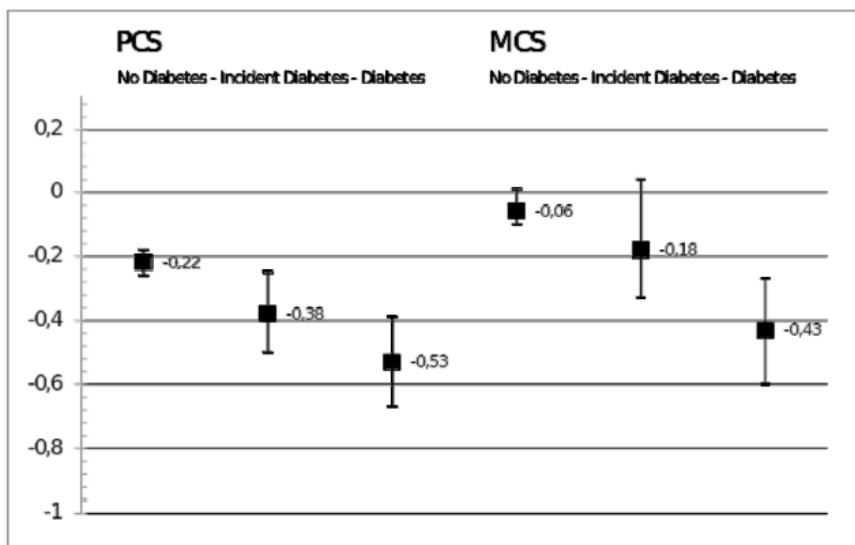

Figure 3: Mean score change (PCS-12, MCS-12) per observation year, adjusted for age, sex and study (Schunk et al. 2017, Fig 2) [1]

Significantly larger mean changes over time in both PCS-12 and MCS-12 scores persisted in people with prevalent diabetes at baseline compared with the group without diabetes, when additionally controlling for socio-economic differences and lifestyle variables. In contrast, declines in mean PCS-12 and MCS-12 scores between incident diabetes and no diabetes groups did not reach significance or were explained in models adjusting for covariables.

This confirmed the results from Hunger et al. (2014), looking at longitudinal changes in HRQL for the transition from normal glucose tolerance via prediabetes to diabetes. Using data from two cross-sectional population-based KORA survey studies (over 7 years from 1999−2001 to 2006−2008), people with normal glucose tolerance (NGT) at baseline who had progressed to diabetes at follow-up experienced a greater loss in mean PCS-12 scores than people with persistent NGT (−7.44 (95% CI −13.09 ; − 1.79) points). However, the decline that was shown for the MCS-12 scores or for both PCS-12 and MCS-12 scores in people progressing from NGT to prediabetes or from prediabetes to diabetes did not reach significance (Hunger et al. 2014).

In summary, our pooled analysis of individual data critically augments the sparse data on HRQL in people with diabetes in Germany with population-based estimates from both regional and national cohort studies. Obtaining reliable estimates for different subgroups, such as between women and men or treatment groups, is urgently needed to investigate the effects of the socio-demographic and clinical characteristics of diabetes. For the first time, this pooled data set provides sample sizes sufficiently large for such key analyses. Our findings point to a significant detriment in PCS-12 scores for people with diabetes, compared with those without diabetes, extending to a detriment in MCS-12 scores for women only. Underlining the importance of cohort studies, longitudinal analysis revealed a much larger diabetes-associated loss of HRQL than estimated using cross-sectional data. Therefore, efforts to improve diabetes management, including evidence-based treatment and advice on self-management, are key to alleviate the diabetes burden on afflicted patients. Our assessment of the status quo and time trends in the quality of diabetes care will be outlined in the following.

4. Self-management and Quality of Diabetes Care

Health care systems increasingly attempt to deal with chronic diseases by standardising treatment and clinical practice, such as using treatment guidelines and the introduction of structured care processes, i.e. DMPs. Within the framework of such programmes, evidence-based protocols for treatment, care coordination and patient education have been introduced. Diabetes was one of the first diseases for which such programmes were established in Germany, starting in 2003. Diabetes care and burden of disease have been examined in KORA cohort studies since 1997/1998, drawing on the KORA diabetes questionnaire, a standardised and field-tested tool to assess patient-related information on diabetes care. Together with other parts of the survey, conveying information on socio-demographics, medical examinations, medication and health-related behaviour, we were thus able to test the relationship between guideline-defined diabetes processes and health outcomes over time.

In an early study, using data from cross-sectional KORA surveys conducted at intervals in 1997−1998 and 2004−2005, we analysed several indicators of diabetes care with a focus on self-management. Robust improvements in participation in educational programmes, knowledge about the disease, physical activity and metabolic outcomes were found (Schunk et al. 2009). Drawing on this evidence, diabetes care arguably moved forward, albeit from very low levels (Icks et al. 2006). We extended the analysis in a subsequent study, comparing cross-sectional KORA survey data from 1999−2000, 2004−2005 and 2006−2008. Improvements were found only with regard to the frequency of at least one foot examination in the past 12 months (37.5% vs. 45.7% vs. 55.1%) and an increase in the intake of medication related to cardiovascular comorbidities or risk factors (anti-hypertensive medications, lipid-lowering medication and platelet aggregation inhibitors) (as shown in Figure 4) (Schunk et al. 2011).
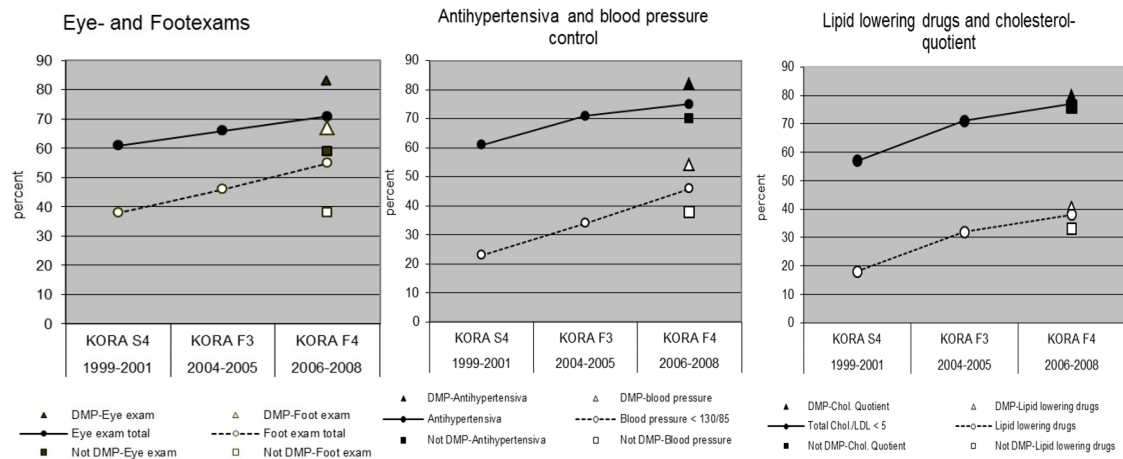
Figure 4: Comparison of time trends under consideration of DMP participation (Figure adapted from Fig 2 in Schunk et al. 2011; Stark et al. 2011)[2]

This may be related to the introduction of diabetes DMPs in 2003. One study compared people in the KORA survey of 2006−2008 who were enrolled in diabetes DMPs with those who were not enrolled (Stark et al. 2011). Summarising indicators of quality of care, people enrolled in DMPs reported appropriate health care processes more often (eyes, feet, cholesterol examination in the last 12 months) and reached certain therapeutic goals more frequently (BP<140/90 mmHg 64% vs. 80%). In general, DMPs may have caused spillover effects that increased the quality of care for all patients with diabetes.

Despite these encouraging findings, other studies drawing on data from this period highlighted shortfalls in the treatment of people with diabetes. For example, a study of pooled data from population-based studies across Germany conducted between 1997 and 2006 identified untreated or insufficiently treated elevated blood pressure targets (>140/90mmHg) in 64% of n=1287 participants with type 2 diabetes mellitus (T2DM). Lipid management was found to be insufficient, with a prevalence of dyslipidaemia (total cholesterol/HDL ratio of ≥5) of 40% (Rückert et al. 2012). Following up these findings in a subsample with longitudinal data, blood pressure values were still higher than target levels in about 50% of people with diabetes after

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6–7 years on average (Rückert et al. 2015). This indicates that treatment regimens to control cardiovascular risk factors in diabetes care are not optimally adjusted, despite their beneficial effects in terms of a reduction in cardiovascular morbidity and mortality.

Using cross-sectional KORA data pooled from two surveys conducted in 2004–05 and 2006–08, it was shown that people with diabetes were well supported by health professionals, as indicated by the number of routine medical examinations, diabetes education and multi-professional care, engaged in higher levels of self-monitoring activities, such as foot care or blood glucose measurement, and revealed higher adherence to professional recommendations concerning diet (Schunk et al. 2015b). Encouraging patient participation, e.g. by shared decision-making styles, in diabetes treatment increases patients' understanding and motivation to follow up on recommended activities, as shown by Heisler et al. (2009) in a US-based study. However, in our study, the intensity of care processes, treatment satisfaction or the perceived quality of the patient–physician relationship were not associated with higher levels of adherence regarding other recommendations, such as medication, foot care and physical activity, or with health behaviour itself. Physical activity levels were very low, with only 15% reporting regular physical exercise.

A later analysis, widened to include KORA survey data from 2013–2014, found no changes in self-management and few changes in physician-delivered care (increase in reported annual HbA1c examinations from 2000 (29%) to 2007 (53%) to 2014 (72%)). On the other hand, a substantially increased proportion of people reached targeted goals for glycaemic control, blood pressure control and HDL cholesterol (Laxy et al. 2016). Observed improvements in this study were larger when comparing 2007 with 2000 than when comparing 2014 with 2007. Over a period of 10 years, from 2004/5 to 2014, the percentage of survey participants with T2DM who reported not having received advice on diet or physical exercise or ever participating in patient education has remained unchanged at around 50% (Laxy et al. 2016; Schunk et al. 2015b).

Patient time spent on self-management, drawing on data from the KORA diabetes questionnaire in the 2013–2014 survey, has been calculated to amount to ~2.5 h (149 min)/week (95% CI 119–181) (Icks et al. 2019). This is much less than what has been

estimated to be needed, if recommendations, as established in guidelines, are adhered to (Russell, Suh, and Safford 2005), and also significantly less than reported in a US study from 2000/1, where patients reported spending a median of 48 min/day (Safford et al. 2005).

In the analysis of KORA data, the different types of self-management activities were divided into disease-specific clinical activities such as measuring blood glucose and blood pressure, taking medication and foot and skin care, and lifestyle-related activities such as exercise, shopping and cooking. The resulting time expenditures are shown in Figure 5. People with insulin or oral anti-hyperglycaemic drug treatment, better diabetes education, HbA1c 48 to <58 mmol/mol (6.5% to <7.5%), lower quality of life as well as an overall healthier lifestyle and more social support (being married or living with a partner) spent more time on self-management activities (Icks et al. 2019). These findings support the hypothesis that lower capacity may disrupt the patients' ability to adequately care for the demands of the illness.
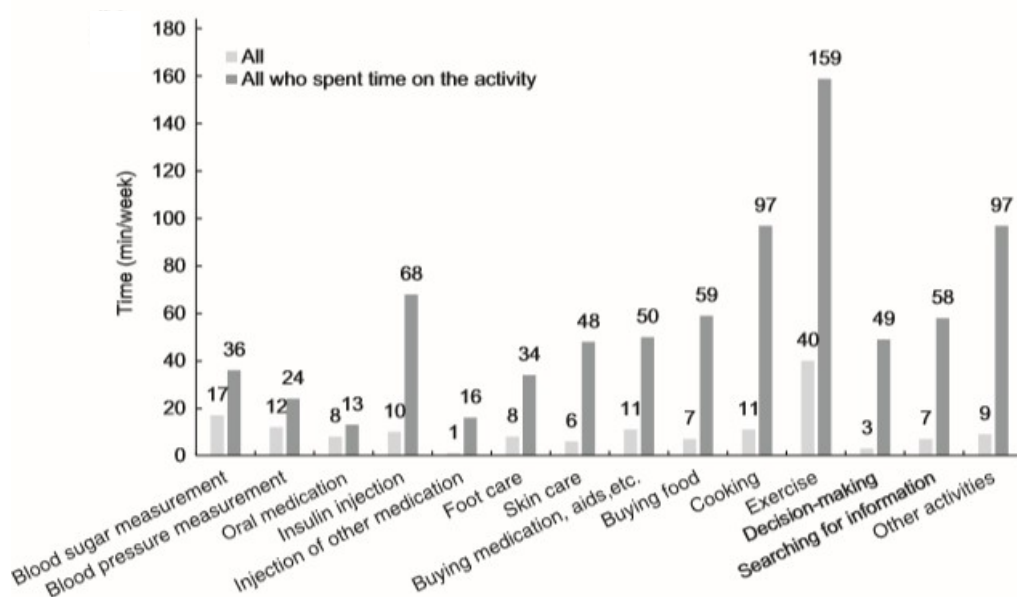

Figure 5: Time spent on diabetes-related self-management activities in KORA survey participants (*light grey: mean time on average across all respondents; dark grey: mean time on average across all of those who endorsed time for the respective activit*y) (Icks et al. 2019, Figure 2b)[3]

The importance of strengthening self-management in patients with T2DM was underlined in a further study using data from a KORA survey in 1997–1998, which estimated the effect of self-management on mortality. Quantifying the extent of self-management using a published index (Arnold-Wörner et al. 2008) at baseline, it was shown in a 12-year mortality follow-up of a sample of 340 people with diabetes that people with strong self-management behaviour had a 39% reduced risk of dying from all causes (HR 0.61 (0.40–0.91)) within the observation period, controlling for intermediate clinical outcomes (e.g. microalbuminuria, polyneuropathy, LDL cholesterol, blood pressure) (Laxy et al. 2014b).

Overall, empirical evidence on the association between care processes and clinical outcomes remains inconclusive. More research should be directed to understand the associations between self-management, health literacy and care processes, as well as their effect on clinical outcomes. Following the evidence that population-based KORA data illustrate for the south of Germany, it can be assumed that improvements have flattened out. This prompts an urgent call for renewed efforts to increase the frequency of care processes and to strengthen patients' support from health professionals.

As monitoring of care processes and outcomes needs to continue with population-based data as well as clinical samples, we must pay heightened attention to inequalities in diabetes management. Patient groups with low individual SES and residential area deprivation receive lower levels of care (Grintsova, Maier, and Mielck 2014; Maier 2017). Regional differences in diabetes treatment, e.g. in the use of new anti- hyperglycaemic drugs, have been shown to be significant after adjustment for SES and regional deprivation and are still largely unexplained (Bächle et al. 2018; Tamayo et al. 2014b). Often overlooked populations such as people in institutionalised care, e.g. suffering from dementia, need further research (Sinclair et al. 2018). Claims data from the AOK Bavaria Statutory Health Insurance for the years 2005–2006 revealed very low levels of diabetes-related medical examinations in people with dementia, which decreased even further after nursing home placement (Schwarzkopf, Holle, and Schunk 2017).

5. Conclusions and Outlook

Starting from the proposition to strengthen patient orientation in health services research, this summary of research findings in the field of diabetes care adds to this aim in several ways. We were able to show that diabetes-associated loss of HRQL is much greater in a longitudinal perspective than assumed from cross-sectional analysis. Drawing on results from our studies with the SF-12, the decreased diabetes-related HRQL in women is associated with diabetes treatment regimens (Schunk et al. 2015a).

Population-based data on HRQL, such as presented herein, drawing on pooled data from regional and one national cohort studies in Germany, are essential to estimate disease burden and to derive priorities for health care policy. Uniquely, these survey data extend the measurement of disease burden to people not accessing health services. Although previous studies mostly relied on cross-sectional data, we were able to better elucidate the true disease burden of type 2 diabetes by analysing longitudinal data, where individual trajectories of prevalent and incident cases can be followed. Further research should focus on longitudinal studies, augmenting generic with diabetes- and treatment-specific instruments.

The high prevalence of comorbidities, such as CVDs and neuropathy, and late-stage complications impose a heavy physical and psychological burden on people with type 2 diabetes. With our findings, we were able to point to a halting of earlier improvements in the last 5–10 years and still very low levels of patient activation (Schunk et al. 2017). As there are hopes for interventions such as lifestyle modifications and pharmacotherapy to prevent diabetes in high-risk individuals, our studies point to the fact that current diabetes care in Germany needs to improve, both in adhering to guideline-defined processes but also in engaging the patient in disease management (Laxy et al. 2016; Schunk et al. 2009; Schunk et al. 2011).

The KORA diabetes questionnaire offers valuable data on patient-reported process and outcome indicators that go beyond specific clinical interventions, thereby integrating components that are guided by the patients themselves, such as questions on self-management and the novel assessment of patient time. Owing to

their long-standing operation as a cohort study starting 30 years ago with multiple follow-up studies, the KORA data allow cross-sectional and longitudinal analyses. Because of their important role in contextualising findings from clinical studies and secondary data analyses, such as from routinely collected data, the use of research-orientated data drawn from population-based cohort studies with multiple waves of data should be expanded. Generally, research should routinely analyse effect mediation and effect modification by gender, such as a recent analysis from Du et al. (2019). More studies should elicit patient preferences, drawing on psychometric instruments, for different health outcomes, e.g. on the benefits and harms of treatments in subgroups of patients, to further our understanding of patient-important outcomes (Ashman et al. 2019). PROM instruments that may be sensitive to gender differences should be prioritised in future research.

More research is needed to strengthen the understanding of which factors are most important for enhancing self-management and clinical outcomes, including patient expectations, attachment styles, self-efficacy and professionals' patient-centredness (Serrano et al. 2016; Strawbridge et al. 2017), and studies will have to draw on a combination of both quantitative and qualitative approaches (Mead and Bower 2000; Nutting et al. 2007).

On a health system level, further efforts are needed to incentivise quality of care improvements drawing on patient-important outcome measures (Du et al. 2015; Glasgow, Peoples, and Scotland 2008; Greenhalgh et al. 2018). Service development should aim at organisational attributes that impact patient-centred health care delivery with a focus on how they help patients to gain positive control over aspects of their illness, e.g. more integrated forms of services ensuring access to and continuity of care (Schunk et al. 2015b).

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Part II Publications

The cumulative habilitation is based on the following original publications:

Quality of Life in Diabetes in Cross-sectional and Longitudinal Perspective

Schunk, M., Reitmeir P., Schipf, S., Völzke, H., Meisinger, C., Thorand, B., Kluttig, A., Greiser, K.H., Berger, K., Müller, G., Ellert, U., Neuhauser, H., Tamayo, T., Rathmann, W., Holle, R.: Health-related quality of life in subjects with and without type 2 diabetes: pooled analysis of five population-based surveys in Germany. Diabetic Medicine. 2012; 29(5):646–53. https://doi.org/10.1111/j.1464-5491.2011.03465.x

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Self-management and Quality of Diabetes Care

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Danksagung