Self-reported health care utilization: measurement issues, data validity and implications for design of health surveys and economic evaluations

An empirical investigation among patients with diabetes mellitus

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vorgelegt von Nadezda Chernyak

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Gutachter

1. Prof. Dr. rer. pol. Heinz Rothgang

2. Prof. Dr. med. Dr. P.H. Andrea Icks

Summary

Background

Researchers as well as public policy makers often have to rely on self-reported health care utilization. Considerable work is usually undertaken in individual projects to develop self-report tools (i.e. questionnaires or diaries) collecting data on health-related resource use. Yet, these tools and results of their validation are seldom published and there seem to be a tendency to develop new questionnaires for new studies. Systematic search for published and validated self-report instruments capturing health care utilization verified these observations. Methods and results of systematic literature search and overview of identified instruments are presented and discussed in Chapter 3. A validated generic questionnaire or at least a standard set of questions on various categories of health care utilization available for German investigators was not found. Published validated diabetes-specific German questionnaire(s) to collect data on health-related resource use were also not identified.

Objective

Overall objective of the present work is (i) to elaborate a set of questions on health care utilization and other health-related resource use (e.g. patient time spent on receiving health care, patient out-of pocket expenditure, work days lost) available “off-the-shelf” for use in German health surveys and economic evaluations alongside clinical trials in order to avoid unnecessary duplication of effort, and (ii) to contribute to the standardization of data collection methods and comparability of results across different studies. Specific objectives: 1. In order to develop a generic questionnaire on health-related resource use, which can be used in various populations, and a set of diabetes-specific questions, taking into consideration the results of systematic review of self-report instruments. 2. To pretest the questions in order to identify possible comprehension problems and processing difficulties and to improve/change questions if necessary; 3. To develop design and methods for a validation study quantifying the accuracy of self-reported data collected by means of developed questionnaire.

Methods and results

The process of the questionnaire development is described in Chapter 4 and the resulting questionnaire (Generic and diabetes-specific modules) is presented in Attachment I. This questionnaire was tested in patients with diabetes mellitus type 1 and type 2 using behavior coding and cognitive interviewing in order to evaluate the performance of questions and to inform possible revisions. Design and results of the pretest are reported in Chapter 5. A revised questionnaire is shown in Attachments III and IV. To develop the design and methods of a validation study providing quantitative evidence on the accuracy of self-reported health care

utilization collected by the questionnaire, theoretical considerations and empirical evidence with regard to validity of self-reported health-related resource use were reviewed. This is described in detail in Chapter 6. Design and methods of a validation study which is currently being carried out are described in Section 6.3.

Discussion and outlook

A number of studies quantified the extent of self-report inaccuracy in terms of variable error and bias; yet only few studies investigated how to improve accuracy of self-report and to minimize bias. Studies using experimental methods, for example, randomized allocation of different questionnaire modes to participants are lacking. Considering that methods of data collection (e.g. data collection interval, mode of administration) differ substantially with regard to their cost, more experimental studies are needed to better quantify the benefits of various methods and to further standardize the questions on health-related resource use. To this end, it was decided to validate the questionnaire for two different recall periods applying an experimental design.

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1. Background

1.1. General background

Data on health care utilization (e.g. hospitalizations, use of outpatient health services, medication use) is required for several reasons. For example, to analyze service use patterns, to identify "underuse" or "overuse" of health care services, to assess health care needs and/or health-related costs. Data on health care utilization may be obtained from various sources: health insurance claims, disease registries, provider records, patient self-report, and expert opinion. Table 1 summarizes strength and limitations of various data sources which can provide information on health-related resource use.

In principle, if detailed information is required, provider records may be a better source of utilization data than burdening patients with a detailed data collection procedure by means of a diary, a written questionnaire or an interview (Johnston *et al.*, 1999). In practice, however, provider records are often difficult to access or retrieve, because (i) it may be necessary to contact many different providers and (ii) patient's consent may be required but not forthcoming. Often, the same limitations to data availability apply for health insurance data as well, in particular, if linking health insurance data to other data sources (e.g. data from a clinical trial or a survey) is necessary. Accuracy/completeness of administrative data is also a concern when providers are in a capitation fee system and have little financial incentive to record diagnoses and services accurately (Bhandari and Wagner, 2006). Moreover, information on utilization of health services not covered by the health insurance and on the non-medical resource-use (e.g. patient's or caregiver's time) is usually not available from health insurance or provider records.

Hence, researchers as well as public policy makers often have to rely – at least in part – on self-reported health care utilization. Considerable work is usually undertaken in individual projects to develop self-report tools (i.e. questionnaires or diaries) collecting data on health-related resource use. Yet, these tools and results of their validation are seldom published and there seem to be a tendency to develop new questionnaires for new studies (Bertoldi *et al.*, 2008; Paterson and Britten, 2005). Bertoldi et al. (2008) conducted a review of the methodologies used in household surveys on medication use (61 studies published between January 1995 and June 2008 were included to the review). They showed that only 30% of the studies published the questions used to assess medication use; and 93.4% of the studies did not provide any information on the validity of the questionnaire employed to collect data on medication use. In this context the question of validity of health care utilization reported in single studies and comparability of results across studies arises.

Table 1: Main strength and limitations of various methods to capture health care utilization

Data source	Available data / Possibilities of data use	Strengths / Benefits	Limitations / Issues of concern
Administrative and health insurance claims data	Patients-specific information on a wide range of healthcare services and acquired medication can be obtained; Procedure codes and dates of service permit the researcher to aggregate costs by type of service and to identify discrete episodes of care; Data can be used to evaluate spending in a calendar year for all individuals with a specific condition (prevalence costs); Data can be linked longitudinally for enrolled individuals with a specific condition to evaluate service utilization and spending following initial diagnosis (incidence costs).	Data for large populations, covering long periods of time, so that service use and costs can often be tracked longitudinally; Data for subgroups such as the institutionalized and cognitively impaired that tend to be underrepresented in surveys can be obtained; Data are less costly to acquire than primary data because they have already been collected for other purposes.	Data are not collected for research purposes and do not always coincide with research needs; Misclassifications in diagnoses can occur, leading to substantial biases; Claims may contain biases due to provider efforts to maximize payment; Clinical data are very limited, which often require linking the data to other data sources to allow meaningful analysis; Data apply only to specific enrolled populations, so that sample selection may occur; Lack of coverage continuity may be a relevant problem for longitudinal analyses; Data limited to covered services.

Medical records (e.g. GP records)	Patient-specific information on provided healthcare services and prescribed medication	Detailed resource-use information can be obtained without burdening patients	Data are not collected for research purposes and do not always coincide with research needs (poor completion, missing files and illegible entries are possible); Patient's consent may be required not access the data but not forthcoming; A multi-sector picture requires exploration of the records of many different providers: Records may be difficult to retrieve and record searches can be time consuming.

Data source	Available data / Possibilities of data use	Strengths / Benefits	Limitations / Issues of concern
Patient self-report	Patients-specific information on health care use, including data on health care utilisation not covered by health insurance as well as data on non-medical resource-use (e. g. patient’s or informal caregiver’s time)	Obviate the need to contact different providers or agencies (e.g. multiple third party payers) to obtain resource-use or cost data	Potential biases introduced by self-report (e.g. non-response, underreporting, overreporting); Limited possibilities to gain longitudinal utilization data due to recall problems; Limited possibilities to gain detailed information on intensity of resource utilization; usually units of resource consumption suitable only for gross-costing can be obtained
Expert opinion	Non-patient specific resource use; Can be used in conjunction with a Bayesian approach to elicit prior beliefs and knowledge about resource use.	Useful when few data exist, for example to estimate cost for rare events.	Recall bias; Bias from cognitive heuristics

1.2. Specific background

Studies conducted in the USA found higher overall health care cost in patients with diabetes and comorbid depression compared to patients with diabetes only. Egede et al. (2002) reported 4.5-times greater total annual health care costs for Medicare patients with comorbid diabetes and depression than for nondepressed patients with diabetes ($247,000,000 and $55,000,000, respectively; $P < 0.0001$ (cost adjusted to reflect August 2001 dollars). Higher costs were explained mainly by increased utilization of general medical services rather than by mental health treatment costs alone. This association persisted even after accounting for comorbid medical conditions. These data identify the potential for cost-offsets through improved treatment of depression in patients with diabetes. To study the specific impact of depression treatment on medical utilization and cost, economic data from experimental studies (RCTs) are needed. Consequently, the question of how to collect accurate data on health-related resource use arises. For reasons already outlined above (see the section 1.1) patient self-report is often the only available source of information allowing to collect data on various categories if health-related resource use (formal and informal health care services, non-medical resource use) alongside RCTs.

2. Objectives

Overall objective of the present work is

(i) to elaborate a set of questions on health care utilization and other health-related resource use (e.g. patient time spent on receiving health care, patient out-of pocket expenditure, days of work lost) available “off-the-shelf” for use in German health surveys and economic evaluations alongside clinical trials in order to avoid unnecessary duplication of effort, and

(ii) to contribute to the standardization of data collection methods and comparability of results across different studies.

Specific objectives:

1. To conduct a systematic review of available self-report tools capturing health care utilization and other health-related resource use with a particular focus on validity of identified instruments;

2. To develop a generic questionnaire on health-related resource-use, which can be used in various populations, and a set of diabetes-specific questions, taking into consideration the results obtained under the objective 1;

3. To pretest the questions developed under objective 2 in order to identify possible comprehension problems and processing difficulties (e. g. respondents interpreting the same question in different ways, or in the same way but not in the way intended by researches; respondents unwilling or unable to retrieve the information necessary to answer the question) and to improve/change questions if necessary;

4. To develop design and methods for a validation study quantifying the accuracy of self-reported data collected by means of questionnaire developed under the objective 2.

3. Systematic review of self-report instruments capturing health care utilization and other health-related resource use

3.1. Methods

The systematic literature search was conducted following an 8-step approach (Droste *et al.*, 2010; Droste and Dintsios, 2011) which includes (1) the conversion of the research question into a searchable question, (2) conceptualization, (3) identification of synonyms, (4) selection of relevant information resources, (5) development of search strategies, (6) implementation of search strategies, (7) saving and documenting the results, and a (8) final quality check.

Every information retrieval process should begin with the conversion of the research question into a searchable question. The aim of this step is to define the relevant search components. Often, the PICO scheme (P = Patient or problem, I = Intervention, C = Comparator and O = Outcomes) (Schardt *et al.*, 2007) is used for this purpose supplemented by additional components if necessary. However, methodological research questions often require different strategy to define the relevant search components.

For the purpose of the literature search implemented in the present work the PICO scheme had to be modified: P would stand now for the *purpose* of the identification of self-report instruments capturing health care utilization and other health-related resource use. I (and C) would be the identified instrument dealing with self-reported health-related resource use. The respective outcome is health care utilization or health-related resource use.

The second step of building a concept by modeling (i.e. defining search components) and linking the defined search components followed step 1. For the linkage of search components the conventional Boolean operators “AND” and “OR” were used including specific adjacent combinations and limitations.

In step 3 synonyms were identified depending on the defined search components and MESH terms revealed in respective digital databases. Different spelling, inflected forms, and definitions of terms were considered (Droste *et al.*, 2010).

MEDLINE (Medical Literature Analysis and Retrieval System Online) and the database Methods Studies (The Cohrane library) were considered to be a valid information source for the research question under study (step 4).

For each of the defined search components (step 1) a search strategy consists of the identified synonyms (step 3). Step 5 requires identifying thesaurus terms related to the synonyms and complementing them by free text queries. The respective thesaurus terms were searched for in MEDLINE and the Cochrane library.

In step 6 the execution of the search followed. Wild cards and truncations (syntax- and provider-specific rules) proximity operators, translations, and syntax rules were taken into account for the search in MEDLINE. The first search started in February 2009 and was updated every half-year. The last update was performed April the 4th 2011.

The retrieved results were saved in a reference management tool (step 7). The reference management tool (Endnote) is essential for a standardized documentation and presentation of the search results. The identified records including their complete references are saved in the reference management tool. Duplicates were deleted.

Finally, the last step contains a final quality check and calculation of precision (Baeza-Yates and Ribeiro-Neto, 2005). The overall number of retrieved records (without duplicates) is known and the publications included in an assessment are also known. The number of the identified relevant publications is related to the overall number of identified records. The result is a rate named precision, commonly expressed as a percentage (A/A+B, where A = identified relevant records and B = identified not relevant records).

3.1.1. Criteria for the inclusion of publications

Criteria defined to include relevant publications into the review are outlined below.

Population

Individuals who were reporting on their own health care utilization and other health-related resource use;

Proxies or caregivers or health care professionals were not considered being part of the investigated population;

Respondents had to be over 18 years old (adults);

Only respondents from high income countries were considered to allow for comparisons with Germany;

Instruments

Interviews or survey questionnaires or diaries or any other tools capturing self-reported health care utilization and other health-related resource use;

Self-report instruments (specified above) had to be described with regard to their content, development and/ or validation;

Outcomes

The outcomes investigated were different categories of health care utilization and other health-related resource use gathered by self-report instruments (e.g. medication, ambulatory visits, hospital stays, time spent on receiving health care, out-of-pocket expenditure, etc.)

Publication type

The studies should have been published after 1990 to ensure the retrieval of relatively up to date/state of the art instruments;

Publications should be available or at least refer to an available instrument;

Animal studies were excluded;

The resulting inclusion and exclusion criteria are summarized in the Table 2.

Table 2: Inclusion and Exclusion Criteria

Inclusion criteria	
I1	Publication time 1990 - current
I2	Implementation and description of a relevant self-report instrument capturing health care utilization and other health- related resource use
I3	Development and/or validation of a comprehensive self-report instrument capturing health care utilization and other health-related resource use
I4	Adult population (> 18 years old)
I5	Patient or general population
I6	High income countries
I7	Full Text Publication language (German, English, French, Spanish, Dutch)
Exclusion criteria	
E1	Duplicate publications not containing relevant additional information
E2	Exclusively evaluation of administrative data or other irrelevant data source or unstated data sources
E3	Reviews or discussion papers
E4	Animal studies
E5	No full-text publication available

The aim of the literature search was to identify full-text published studies that provided relevant information on the development, implementation and/or validation of self-report instruments capturing health care utilization and other health-related resource use.

3.1.2. Identification of relevant publications

The identification of relevant publications was realized in a two-step approach

1. *Title and abstract screening of the retrievals from digital databases (MEDLINE, Cochrane)*

The citations identified in the defined bibliographic digital databases were evaluated with regard to their relevance on the basis of their titles, and, if available, their abstracts. Publications viewed as potentially relevant were perused with regard to their relevance using the full text.

2. *Assessment of potentially relevant full text publications*

The assessment of the relevance of the identified publications was done on the basis of the full text. Additionally the reference lists of relevant publications were searched in order to identify any further relevant publications. The publications to be included were screened with regard to whether they represented multiple publications of the same study. In that case all the multiple publications were allocated to the corresponding study.

The next tables contain the documentation of the search strategies implemented in MEDLINE and Cochrane Library.

3.1.3. Documentation of search strategies

Databank: Medline (OVID)

Time span of search: 1990 – 2011

Date of the latest update: 2011.04.04

#	Hits	Search Steps
1	115184	UTILIZATION.fs.
2	9014	"UTILIZATION REVIEW"/ or exp "DRUG UTILIZATION REVIEW"/
3	344971	(instrument* or scale or measure* or questionnaire* or inventory or interview or survey or patient diary).m_titl.
4	120183	1 or 2
5	6068	3 and 4

6	1593	5 and (visit or visits or medication* or 'number of' or 'proportion of').ti,ab.
7	293	6 and (utilisation or utilization).ti,ab.
8	37987	exp HEALTH SERVICES/UT [UTILIZATION]
9	45616	2 or 8
10	14698	9 and (visit or visits or medication* or 'number of' or 'proportion of' or out-of-pocket or expenditure*).ti,ab.
11	4157	10 and (instrument or scale or inventory or measure or survey).ti,ab.
12	143	11 and ('use' or utilisation or utilization).ti. and self-report*.ti,ab.
13	115	10 and ((instrument or scale or inventory or survey) adj3 ('use' or utilization or utilisation)).ti,ab.
14	18438	HEALTH CARE SURVEYS/
15	2336	9 and 14
16	1400	15 and (instrument or scale or inventory or measure or survey).ti,ab.
17	382	16 and ('use' or utilisation or utilization).ti.
18	38	((resource utilization or resource utilisation or care utilization or care utilisation or medication utilization or medication utilisation or resource consumption or therapy utilization or therapy utilisation or health service utilization or health service utilisation or 'resource use' or 'service use' or 'healthcare use' or 'health care use') adj3 (instrument* or scale or measure* or questionnaire* or inventory or interview or survey or patient diary)).ti.
19	829	((utilization or utilisation or 'use') adj (instrument* or scale or measure or questionnaire or inventory or survey)).ti,ab.
20	57	19 and (resource utilization or resource utilisation or care utilization or care utilisation or medication utilization or medication utilisation or resource consumption or therapy utilization or therapy utilisation or health service utilization or health service utilisation or 'resource use' or 'service use' or 'healthcare use' or 'health care use').ti,ab.
21	162	(((((haemophilia utilization group study or rud lite or complementary) and alternative medicine us* survey) or resource utilization questionnaire or resource utilisation questionnaire or health service us* scale or medical resource us* questionnaire or health) and social service utilization questionnaire) or stanford health assessment

		questionnaire or health survey utilization scale).ti,ab.
22	113	(resource use* inventory or health service utilization inventory or health utilization questionnaire or service receipt inventory or services utilization survey or medication us* survey or alternative health care us* questionnaire or (service assessment for children and adolescents) or saca or (aids cost and service utilization survey) or acsus or health services utilization survey or family health utilization survey).ti,ab.
23	77	(resource utilization in dementia or resource utilisation in dementia or rud-foca or resource utilization in dementia-formal care or instrument for measuring informal care or rui).ti,ab.
24	75	(advanced illness index or outreach motivational interviewing or taiwan triage system or (canadian triage adj acuity scale) or emergency severity index or baseline resource utilization form or fs-too or resource utilization substudy or health care utilization questionnaire or healthcare utilization questionnaire or weighted hospital days scale or whd-94 or resource utilization system or rug t18 or patient cost diary or resource intensity scale or (scottish health service resource utilization groups adj2 measure) or health resource utilization assessment).ti,ab.
25	133	1 and ((instrument or scale or inventory) adj3 ('use' or utilization or utilisation)).ti,ab.
26	1449	7 or 12 or 13 or 17 or 18 or 20 or 21 or 22 or 23 or 24 or 25
27	1268	limit 26 to (humans and yr="1990 -current")

#	Hits	Suchtext
1	115184	UTILIZATION.fs.
2	9014	"UTILIZATION REVIEW"/ or exp "DRUG UTILIZATION REVIEW"/
3	344971	(instrument* or scale or measure* or questionnaire* or inventory or interview or survey or patient diary).m_titl.
4	120183	1 or 2
5	6068	3 and 4

Databank: Methods Studies (The Cochrane library (Wiley))

Time span of search: unlimited

Date of the latest update: 2011.04.04

#	Hits	Search Steps
#1	154	(utilisation or utilization) in Methods Studies
#2	18	(resource use):ti in Methods Studies
#3	172	#1 OR #2

3.2. Results

The primary systematic literature search in the defined bibliographic digital databases including all search updates within the last two and the search in systematic reviews yielded a total of 1341 hits. 1268 were derived from MEDLINE directly, 15 from the Methods Studies databank of the Cochrane library. Another 36 were retrieved in MEDLINE by snowballing search for pre-identified instruments and finally 23 in the same databank again by snowballing search for pre-identified systematic reviews and HTA on the topic of interest. After the exclusion of 29 duplicates 1313 publications remained to be screened.

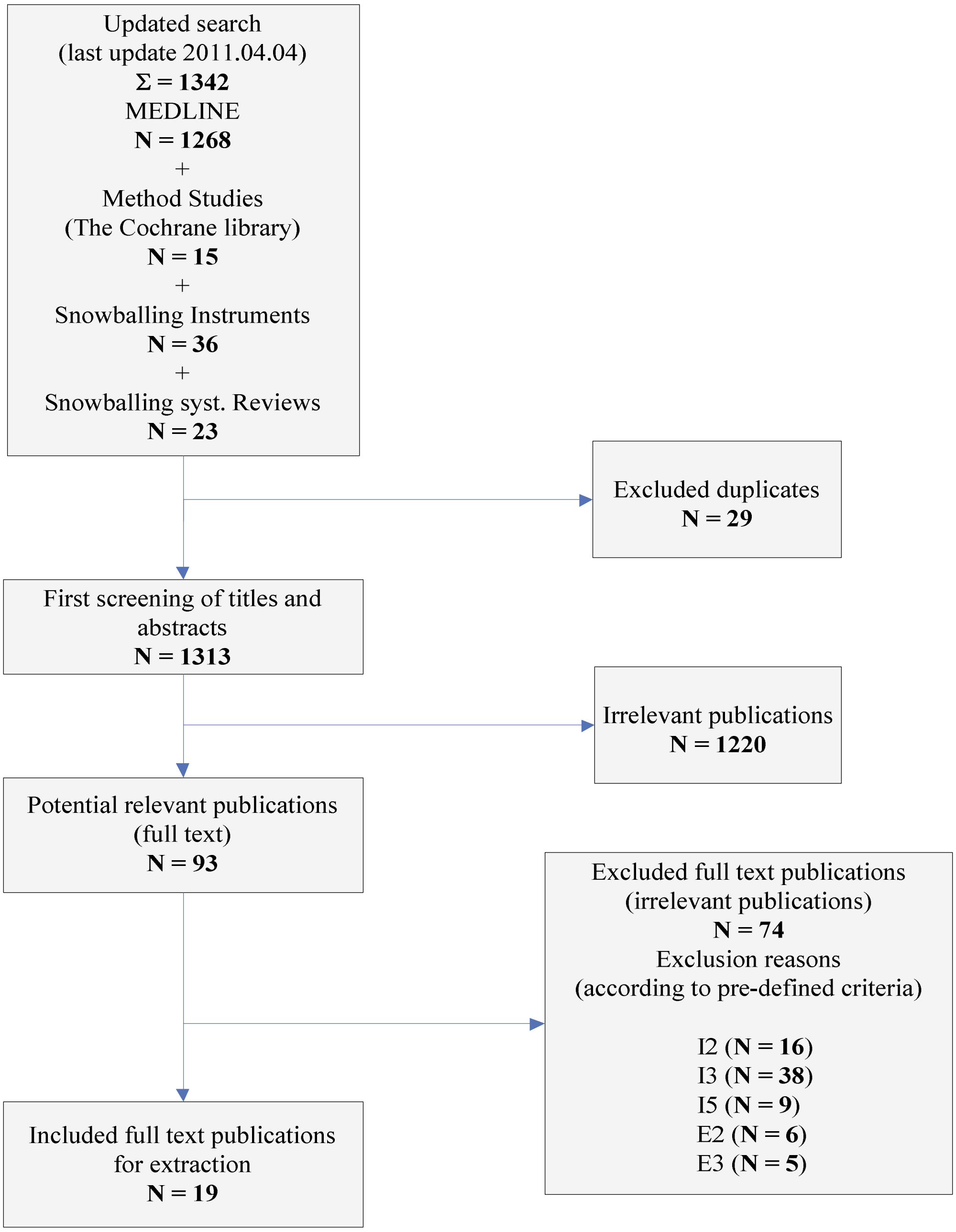
After the first screening of title and (if available) abstract of the publications 93 were considered to be potentially relevant for the research question of interest. The remaining 1220 hits were categorized as not relevant. For these 93 publications full text publications were ordered. All the 93 full text publications were available at the German Central Library for Medicine in Cologne (ZBMED) either in digital format or as a hard copy.

After full text screening 19 publications fulfilled all the inclusion criteria and none exclusion criterion. 38 of the 93 full text publications contained only information about the application of a self-report instrument or only single questions without any explicit information about the instrument. In 16 publications even the application of the particular instrument was not described or the instrument was irrelevant for the research question under consideration. 9 of the 93 full text publications dealt with instruments collecting data from proxies (e.g. caregiving relatives) or health professionals. 6 studies collected data on health-related resource use from administrative or other irrelevant data sources. The remaining 5 of the 93 full text publications were either systematic reviews or discussion papers.

For the latest literature search update in April 2011 including all the retrieved records (without) duplicates precision was calculated to be about 2% indicating the formulation of a rather sensitive search strategy with poor precision. A high precision would put the systematic literature search at risk of losing some important hits. Given that only few relevant publications were found, missing even a small proportion of them would lead to a substantial information loss.

The following figure depicts the flow chart of the literature search documenting the respective hits and the exclusions and inclusions of the identified publications based on the pre-defined criteria.

Figure 1: Flow chart of the systematic literature search



3.2.1. Results of full text screening

A Included studies

1. Byford S, Leese M, Knapp M, Seivewright H, Cameron S, Jones V, Davidson K, Tyrer P. 2007. Comparison of alternative methods of collection of service use data for the economic evaluation of health care interventions. Health Economics 16(5):531-6.

2. Chisholm D, Conroy S, Glangeaud-Freudenthal N, Oates MR, Asten P, Barry S, Figueiredo B, Kammerer MH, Klier CM, Seneviratne G, Sutter-Dallay AL, Group T-P. 2004. Health services research into postnatal depression: results from a preliminary cross-cultural study. British Journal of Psychiatry - Supplementum.46:s45-52.

3. Chisholm D, Knapp MR, Knudsen HC, Amaddeo F, Gaite L, van WB. 2000. Client Socio-Demographic and Service Receipt Inventory--European Version: development of an instrument for international research. EPSILON Study 5. European Psychiatric Services: Inputs Linked to Outcome Domains and Needs. British Journal of Psychiatry - Supplementum.(39):s28-33.

4. Cooper NJ, Mugford M, Symmons DP, Barrett EM, Scott DG. 2003. Development of resource-use and expenditure questionnaires for use in rheumatology research. Journal of Rheumatology 30(11):2485-91.

5. Goossens ME, Rutten-van Molken MP, Vlaeyen JW, van der Linden SM. 2000. The cost diary: a method to measure direct and indirect costs in cost-effectiveness research. Journal of Clinical Epidemiology 53:688-695.

6. Guzman J, Peloso P, Bombardier C. 1999. Capturing health care utilization after occupational low-back pain: development of an interviewer-administered questionnaire. Journal of Clinical Epidemiology.52(5):419-27.

7. Heinrich S, Deister A, Birker T, Hierholzer C, Weigelt I, Zeichner D, Angermeyer MC, Roick C, Konig HH. 2011. Accuracy of self-reports of mental health care utilization and calculated costs compared to hospital records. Psychiatry Research 185(1-2):261-8.

8. Hulsemann JL, Ruof J, Zeidler H, Mittendorf T. 2006. Costs in rheumatology: results and lessons learned from the 'Hannover Costing Study'. Rheumatol Int 26:704-711.

9. Kashner TM, Stensland MD, Lind L, Wicker A, Rush AJ, Golden RM, Henley SS. 2009. Measuring use and cost of care for patients with mood disorders: the utilization and cost inventory. Medical Care 47(2):184-90.

10. Kashner TM, Trivedi MH, Wicker A, Fava M, Greist JH, Mundt JC, Shores-Wilson K, Rush AJ, Wisniewski SR. 2009. Voice response system to measure healthcare costs: a STAR*D report. Am J Manag Care 15:153-162.

11. Owen-Smith A, Sterk C, McCarty F, Hankerson-Dyson D, Diclemente R. 2010. Development and evaluation of a complementary and alternative medicine use survey in African-Americans with acquired immune deficiency syndrome. J Altern Complement Med 16:569-577.

12. Pinto D, Robertson MC, Hansen P, Abbott JH. 2011. Good agreement between questionnaire and administrative databases for health care use and costs in patients with osteoarthritis. BMC Med Res Methodol 11:45.

13. Quandt SA, Verhoef MJ, Arcury TA, Lewith GT, Steinsbekk A, Kristoffersen AE, Wahner-Roedler DL, Fonnebo V. 2009. Development of an international questionnaire to measure use of complementary and alternative medicine (I-CAM-Q). Journal of Alternative & Complementary Medicine 15(4):331-9.

14. Roick C, Kilian R, Matschinger H, Bernert S, Mory C, Angermeyer MC. 2001. [German adaptation of the client sociodemographic and service receipt inventory - an instrument for the cost of mental health care]. [German]. Psychiatrische Praxis.28 Suppl 2:S84-90.

15. Rosch M, Leidl R, Tirpitz Cv, Reinshagen M, Adler G, Konig HH. 2002. [Cost measurement based on a cost diary in patients with inflammatory bowel disease]. Zeitschrift fur Gastroenterologie 40:217-228.

16. Sano M, Zhu CW, Whitehouse PJ, Edland S, Jin S, Ernstrom K, Thomas RG, Thal LJ, Ferris SH. 2006. ADCS Prevention Instrument Project: pharmacoeconomics: assessing health-related resource use among healthy elderly. Alzheimer Dis Assoc Disord 20:S191-202.

17. Schweikert B, Hahmann H, Leidl R. 2008. Development and first assessment of a questionnaire for health care utilization and costs for cardiac patients. BMC Health Services Research.8:187.

18. Sirey JA, Meyers BS, Teresi JA, Bruce ML, Ramirez M, Raue PJ, Perlick DA, Holmes D. 2005. The Cornell Service Index as a measure of health service use. Psychiatric Services 56(12):1564-9.

19. Zuvekas SH, Olin GL. 2009. Validating household reports of health care use in the medical expenditure panel survey. Health Services Research 44(5 Pt 1):1679-700.

B Not fulfilling inclusion criterion I2 “implementation and description of a relevant self-report instrument capturing health care utilization and other health-related resource use”

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3.2.2. Description of identified self-report instruments capturing health care utilization and other health-related resource use

All articles included into the review were examined based on a structured predefined protocol. For each instrument the following information was extracted (if available): country of development, available language(s), resource use captured (generic or disease specific), number and type of items, recall period, mode of administration, psychometric properties, accessibility of the instrument (included within the publication, available from the authors or in the internet). Below, the identified instruments are outlined according to these criteria.

Self-report instruments described by Owen-Smith et al. (2010) and Quandt et al. (2009) focused exclusively on collecting information about the utilization of complementary and alternative medicine. These two instruments will not be described in detail, since the present work focuses mainly on the utilization of formal health care services.

The Client Service Receipt Inventory, CSRI (Beecham and Knapp 2000)

The Client Service Receipt Inventory (CSRI) is a research tool developed by staff in the Centre for the Economics of Mental Health and the Personal Social Services Research Unit, London, UK, for collecting cost-related information about people with mental health problems for use in mental health service evaluations. The CSRI is a questionnaire which takes approximately 20 minutes to complete and collects retrospective information about the interviewee's use of health and social care services, accommodation and living situations, income, employment and benefits. The service receipt section is the largest part of the questionnaire. Modified versions of the CSRI are widely used in evaluation studies in the UK. Beecham and Knapp (2000) provide and discuss examples of the use of the CSRI in completed research. CSRI is available from www.hsr.iop.kcl.ac.uk/cemh.

Two studies, which applied the modified version of the CSRI and validated some of its domains were found. Byford et al. (2007) applied the CSRI in the Prevention of Parasuicide by Manual Assisted Cognitive-behaviour Therapy (POPMACT) trial – a multi-centre RCT of manual assisted cognitive-behaviour therapy (MACT) for the treatment of adults with recurrent episodes deliberate self-harm compared to treatment as usual – to collect service use by patient self-report (interview) after six and twelve months of the therapy. In addition, data from GP records were collected. For 272 patients data were available from both sources, and included inpatient days, outpatient and accident and emergency (A&E) attendance, and contacts with GPs, practice nurses, community psychologists, community psychiatric nurses and occupational therapists. Agreement between the two data sources was relatively high for GP contacts and

A&E attendances (Lin's concordance correlation coefficient: 0.631 and 0.760 respectively) but relatively poor for all other service types, with agreement levels ≤ 0.40.

Patel et al. (2005) compared the number of GP visits in previous six months reported in a postal survey, incorporating the CSRI to the GP case records. There was a good agreement between the number of GP visits recorded on GP case records (mean 3.03) and on the CSRI (mean 2.99) (Lin's concordance correlation coefficient = 0.756).

Client Socio-demographic and Service Receipt Inventory – European Version, CSSRI-EU (Chisholm *et al.*, 2000; Thornicroft *et al.*, 2006)

The CSSRI-EU is a European version of the CSRI. The CSSRI-EU was developed within the framework of the EPSILON (European Psychiatric Services: Inputs Linked to Outcome Domains and Needs) project and applied in five-country[1], cross-sectional study of people with schizophrenia. The focus of this study was on achieving face validity within and between participating sites. The key domains of the instrument are summarized in the Table 4. The instrument is applicable for use in interview with patients and/or key staff. Studies aiming to assess the accuracy of the self-reported service use obtained by CSSRI-EU were not found.

Table 3: Key domains and variables of the Client Socio-demographic and Service Receipt Inventory – European Version (CSSRI-EU)

Section	Key variables
Socio-demographics	Age, gender, marital status, ethnicity, mother tongue, years of schooling, educational level
Usual living situation	Living situation (alone, with relatives, etc.), type of accommodation, household composition
Employment and income	Employment status, occupational category, days of work lost, state benefits, source/level of income and income
Service receipt	Hospital in-patient days, out-patient/day care attendances, community based service contracts (mental health, social services and primary care), criminal justice service contracts
Medication profile	Name/type of drug, dosage level and frequency

Source: Chisholm et al. 2000

The Client Service Receipt Inventory – Postnatal Depression, CSRI–PND (Chisholm *et al.*, 2004)

CSRI–PND version is a derivation of the CSSRI-EU described above. The instrument brings together questions which should enable the comprehensive costing of care packages for women who are about to have or who have recently had a child, with a view to determining the excess need and service uptake of women with postnatal depression. The instrument also attempts to estimate some of the main economic 'knock-on' effects of postnatal depression, in particular the impact on the income or productivity of the woman or household, and the extra inputs of informal caregivers. A final set of (more qualitative) self-report questions relate to potential barriers to accessing services. The key domains of the instrument are summarized in the Table 4. The questionnaire was developed and administered to a pilot sample in a number of European study centres[2]. Studies aiming to assess the accuracy of the self-reported service use obtained by CSRI–PND were not found.

Table 4: Key domains and variables of the Client Service Receipt Inventory Postnatal Depression

Section	Key variables
Housing	Usual place of residence, size and occupancy of household, adequacy of accommodation for raising a small child.
Employment and income	Assessment of any periods of maternity (and paternity) leave taken or permitted, employment situation and income level of both the mother and her partner, and number of days the mother, her partner and two closest relatives/friends have been absent from/unable to work or carry out usual activities owing to postnatal illness. Key outputs from this section are estimates of overall household income and forgone work/productivity.

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[1] The five research sites were Amsterdam (The Netherlands), Copenhagen (Denmark), London (England), Santander (Spain) and Verona (Italy).

[2] Seven European centres participated in the project: Bordeaux (France), Dublin (Ireland), London (UK), Paris (France), Porto (Portugal), Vienna (Austria) and Zurich (Switzerland).

Use of services	Checklist of key out-patient (and in-patient) services that the mother may have had contact with over a retrospective period of 6 months, including contacts with obstetricians, midwives, primary health care workers, social workers and specialist mental health service professionals. The total number of contacts (or in-patient days) in the previous 6 months is elicited, together with the usual location and average duration of contacts. A corollary to these questions concerning actual rates of use concerns potential barriers to service access or use, such as geographical distance, financial cost, service quality, provider responsiveness and stigma. Different levels of access to care across the participating sites may have an important bearing on the uptake of services.
Child care and pediatric services	The final section documents the normal care arrangements for the new child, together with anyuse of paediatric services over the 6-month retrospective period.

Source: Chisholm et al. 2004

Client Sociodemographic and Service Receipt Inventory – German version (CSSRI-D) (Roick *et al.*, 2001)

The questionnaire is an adaptation of the CSSRI-EU described above to the German health care system. The CSSRI-D facilitates tracking the subject's specific use of health services retrospectively, focusing especially on services for psychiatric patients. It can be easily adapted to fit the purpose of the study with respect to included services and recall time frames.

Heinrich et al. (2011) validated the CSSRI-D in a prospective cohort study in Germany. Self-reports regarding psychiatric inpatient and day-care use were collected by telephone interviews based on the CSSRI-D and compared to computerized hospital records. The sample consisted of patients with mental and behavioral disorders resulting from alcohol (n=84), schizophrenia, schizophrenic and delusional disturbances (n=122) and affective disorders (n=124). Depending on type of service, measure of service utilization agreement ranged from excellent to poor and varied substantially between individuals. The agreement for total duration in days was nearly excellent (Lin's concordance correlation coefficient = 0.7479) and for the total number of admissions fair (Lin's concordance correlation coefficient = 0.5826). With respect to any use of psychiatric inpatient and/ or day-care, agreement was excellent (κ = 0.781). For every service use measure inpatient care showed a better agreement than day-care.

Utilization and Cost Inventory, UAC-I (Kashner et al. 2009a)

UAC-I has been developed and applied in the US. It is a structured patient interview designed to determine use of inpatient and outpatient care over a 3-month period for patients with mood disorders. Unlike structured questionnaires where interviewers follow a script, interviewers are provided guidelines and data capture points to query respondents. Outpatient care is counted as encounters between the patient and a licensed health care professional. Outpatient care is subdivided by specialty (medicine, surgery, psychiatry, dental, treatment for addictions, physical medicine, physical rehabilitation, and vocational rehabilitation) and setting (clinic, telephone call, or off-site to a home, work place, or mobile care station). Emergency room settings are classified by specialty (medicine or psychiatry) and counted as visits. Inpatient care settings are subdivided into bed sections (medicine, surgery, psychiatry, dental, physical rehabilitation medicine, residential treatment, domiciliary and nursing home care, and addictions treatment) and counted as days stayed. UAC manual is available from the authors. UAC-I (Kashner *et al.*, 2009a) extends earlier version (Kashner *et al.*, 1999) by expanding the number of service classes to 33, and offering cost-weights computed from secondary sources, which allows estimation of costs from patient responses.

To validate the UAC-I, it was tested on 212 patients with mood disorder from the outpatient mental health clinics at the Department of Veterans Affairs (VA), North Texas Health Care System (Kashner *et al.*, 1999). Counts (inpatient days and outpatient encounters) and costs (dollars) computed from survey responses were compared with estimates from medical records. The intraclass correlation coefficient (ICC) for inpatient days was 0.97 (95% CI: 0.95–0.99; the ICC for outpatient encounters was 0.74 (95% CI: 0.65– 0.80).

Utilization and Cost Interactive Voice Response Questionnaire, UAC-IVR (Kashner *et al.*, 2009b)

UAC-IVR is a telephone-operated, interactive voice response (IVR) system designed to collect use-of-care data from patients with major depression. It contains scripted questions covering patient use of healthcare during 90-day intervals. The questions are derived from the Utilization and Cost Inventory (Kashner *et al.*, 2009a). Respondents are first asked whether they had used care during the past 3 months (yes or no). Patients who responded "yes" are subsequently asked how much care they had used. Patients are asked about using services classified by setting (outpatient clinic visits, emergency room visits, and inpatient days stayed) and by type (depression related, other-psychiatric, and general medical problems).

To make a call, patients first dial a toll-free number using a touch-tone telephone. The caller receives recorded instructions, followed by a set of questions. After each question, the recorded message prompts patients to respond by pressing an appropriate number on the telephone keypad. The computer then recorded each response and automatically determined the next set of scripted questions to ask the patient. These systems allow for remote data access, automated scoring, patient feedback, and opportunities for self-disclosure of sensitive information.

To validate the UAC-IVR Patient self-reports from repeated IVR surveys were compared with provider records for 3789 patients with major depression at 41 clinical sites participating in the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial. Inconsistent responses were found for 10% of calls and 21% of patients. Underreporting biases (–20%) and moderate agreement (intraclass correlation of 68%) were found when UAC-IVR responses were compared with medical records. IVR reporting biases were less for patients after 3 calls or more (experience), for patients with severe baseline symptoms (motivation), and for patients who gave consistent IVR responses (reliability).

Cornell Services Index, CSI (Sirey *et al.*, 2005)

The CSI was developed to provide a snapshot of service use patterns across types, providers, and sites of service among adults who seek mental health care in mental health clinics in Westchester County, New York, as part of a study funded by the National Institute of Mental Health. The instrument was designed to be a portable, brief method of documenting the services used. The CSI assesses the frequency and duration of use of a range of services over the past three months. Services are aggregated into four types: outpatient psychiatric or psychological, outpatient medical, professional support, and intensive services. Outpatient psychiatric or psychological services include psychotropic medication visits, psychotherapy, diagnostic evaluations, drug and alcohol counseling, and self-help groups.

Resource-Use and Expenditure Questionnaires for Use in Rheumatology Research (Cooper et al. 2003)

Cooper et al. (2003) developed a self-completion and postal resource-use and expenditure questionnaire for use in economic studies of early inflammatory polyarthritis. Information on a wide range of health-related resource use including formal and alternative medical care, forgone work and leisure time, travel, informal care and over-the-counter medication can be collected. The questionnaire was pilot-tested and validated (where possible) against alternative data sources in populations in 2 geographically different areas in the UK.

The reported number of inpatient stays and outpatient visits were validated against information from the HIS for the National Health Service For inpatient stays there was perfect agreement. The kappa statistic of agreement for categorical data between the self-reported and HIS recorded number of outpatient visits per person was 0.58 (based on a total of 8 outpatient visits during the 3-month follow-up period incurred by 5 of the study participants).

Interviewer-administered questionnaire to assess health care utilization after occupational low-back pain (Guzman *et al.*, 1999)

The questionnaire provides extensive information on health care provider visits, investigations, and treatments for LBP. It was tested in subjects (n=80) selected from a stratified convenience sample of workers to represent the spectrum of acute, sub-acute, and chronic occupational mechanical LBP in the province of Ontario, Canada. The questionnaire validity was assessed by comparison with a prospective patient diary and with provider reports. Because of the different response rates the comparison between questionnaire and diary was based on 32 subjects; the comparison with health provider records had to be limited to physician records and to 48 subjects owing to the low response rate from providers. There was moderate to substantial agreement between the interview and the patient diary (k values between 0.38 and 0.78). Overall, subjects reported more health care services to the interviewer than they recorded in the diary. Agreement between interviews and physicians' reports was substantial in use of plain X-rays (k=0.79) and computed tomography scans (k=0.85), but physicians often reported referrals not reported by the subjects. Agreement on prescription medications was fair (k=0.29–0.46). The interviewer-administered questionnaire had better response rate than the patient diary.

Osteoarthritis Cost and Consequences Questionnaire (OCC-Q) for capturing health care use and costs in patients with osteoarthritis (Pinto *et al.*, 2011)

The OCC-Q was designed to capture health care use, patient co-payments, and other out-of-pocket costs related to hip or knee osteoarthritis (OA) over the preceding three-month period. The questionnaire was tested in a clinical trial setting as part of the Management of Osteoarthritis (MOA) trial – a randomized controlled trial investigating the value of physiotherapy in addition to usual care for patients with hip or knee osteoarthritis undertaken in Dunedin, New Zealand. Fifty of the 56 participants in the MOA trial who were invited to participate in the present study agreed (response rate = 89%). The questionnaire asked the participant to recall visits to GPs, public and private hospitals, and any community services received. It also asked about any time off work, copayments or out-of-pocket costs related to OA over the three-month period, and use of osteoarthritis-related medications during the previous week. The questionnaire was first administered per mail and the returned questionnaires were followed-up with a 5-10 minute phone call to each respondent to review his or her responses, in particular, with respect to the study's definition of osteoarthritis-related health care. Respondents were encouraged to define a GP or hospital visit as OA-related if it was a follow-up for their hip or knee complaints, if a significant part of the visit was devoted to their hip or knee complaints, or if the doctor renewed their OA-related prescriptions. OA-related medications were specified as a predefined list of analgesics, anti-ulcerants, and psychotropics in the questionnaire. Interview techniques including prompting, and relating health care consultations to a consequence, such as a prescriptions or referral, were used to improve recall. The patient interview took an average of 8 minutes. Only 1.6% of the data were missing.

To assess the validity of using the OCC-Q it was compared with using administrative databases. Only GP contacts and medications were recorded in sufficient quantities for their quantity data to be analyzed using Lin's concordance correlation coefficient. Concordance levels were fair (0.41) for the number of GP contacts and good (0.63) for the number of medications reported.

Health care utilization questionnaire for administration to patients with rheumatoid arthritis (Ruof *et al.*, 2004; Hulsemann *et al.*, 2006)

The questionnaire – based on the results of the in-depth interviews with patients – includes 12 items in the domains physician visits, outpatient surgery, medication, diagnostic procedures and tests, inpatient costs, and transportation (copy of questionnaire may be provided by authors upon request). The questionnaire was tested in a cohort of RA patients every 4 months for 1 year. To validate the questionnaire, self-reported utilization was compared with corresponding health insurance data. The patients included in the validation study (n=227) were recruited through the private offices of 14 rheumatologists in Lower Saxony, in Germany. The following results were reported regarding the agreement between the two data sources: disease-modifying antirheumatic drug (yes/no, k= 0.68), nonsteroidal antiinflammatory drug (yes/no; k= 0.64), osteoporosis medication (yes/no; k=0.56), analgesic (yes/no; k=0.38), and steroid (yes/no; k=0.83). Imaging: imaging of bones and chest (yes/no; k=0.20). Hospitalization: inpatient episodes (yes/no; k=0.64) and number of inpatient days (spearman's rank correlation coefficient, r = 0.80, $P < 0.001$). Transport: costs incurred (yes/no; k= 0.13) and amount (r = 0.39, $P < 0.001$).

Questionnaire for health care utilization and costs for cardiac patients (Schweikert *et al.*, 2008)

The questionnaire measures disease-related utilization and costs for patients after an acute cardiac event (ACE) over a period of 3 months. The questionnaire was tested on 106 patients, who were admitted for rehabilitation after ACE. In order to test its convergent validity it was compared with prospectively measured data (cost diary); selected items were compared with administrative data from sickness funds. Concordance between retrospective and prospective data showed an intraclass correlation (ICC) ranging between 0.57 for medication and 0.9 for hospital days with the other main items (physician visits, days off work) clustering around 0.7. Comparison between self-reported and administrative data for days off work and hospitalized days were possible for n = 48. Respective ICCs ranged between 0.92 and 0.94. The questionnaire is available at http://www.biomedcentral.com/content/supplementary/1472-6963-8-187-S1.pdf

The Resource Use Inventory, RUI (Sano *et al.*, 2006)

The Resource Use Inventory (RUI) is an instrument that has been developed and used to capture resource utilization and costs in populations with Alzheimer disease. It can also be employed for tracking resource and time use through transition from healthy to cognitive impairment in cognitively intact elderly as they begin to demonstrate cognitive deterioration.

The RUI consists of 9 questions (the questions are included within the article). The first part of the RUI captured subjects' use of direct medical care (e.g., hospitalizations) and nonmedical care (e.g., home health aides). The second part of the RUI captured the time caregivers spend providing care to the subjects. The third part of the RUI captured subjects' participation in volunteer work and employment to ascertain aspects of subjects' time use. The assessment interval for each question is the past 3 months.

The instrument was designed to collect maximum information with little additional assistance from site staff. Studies aiming to assess the accuracy of the self-reported resource use data obtained by RUI were not found.

Cost diary (Goossens *et al.*, 2000)

The diary was developed in order to estimate total resource use, expenses, and lost production due to illness and treatment. It was applied in two randomized clinical trials conducted in the Netherlands and evaluating the cost-effectiveness of behavioral rehabilitation in 205 fibromyalgia and chronic low back pain patients. The patients were asked to complete the diaries for a period of 1 year after treatment. They documented when, where, and how often the activities, consultations, etc., took place within the time period of interest. The validation exercise was limited to the number of physiotherapy contacts and specialist contacts, because other services were financed through capitation systems and it was impossible to trace the individual number of visits in the health insurance records.

Table 5: Components of the cost diary developed by Goossens et al. 2000

Direct health care costs	Visits to the general practice, specialist care, alternative medicine, and physiotherapy, days of hospitalization, and prescribed medications.
Direct non-health care costs	Costs of over-the-counter medication, costs of health activities, hours of paid and unpaid household help, transportation, other out-of-pocket expenses.
Indirect costs	Number of days lost from (paid and unpaid) work and days lost from housekeeping and other daily activities.

50 percent (103) of the respondents completed the diary for the entire year of follow-up, 85 percent of the patients completed at least one diary and in total 68% of the diaries were returned. Response rates were not significantly related to gender, education, age, pain, coping, duration of pain, depression, social desirability, and quality of life. Self-reported specialist care contacts were generally in agreement with the health insurance data. The mean number of contacts to a specialist (any specialist as long as the contact was related to the back pain) based on the data from the insurance company was 1.20 (SD 1.49) per year. Using the cost diary the estimated number of contacts was 1.25 (SD 2.01) visits per patient per year. Nonparametric tests indicated no significant difference between the two methods (P = 0.930). The average number of visits to the physiotherapist, as recorded in the diaries (5.40; SD 14.47) was significantly different from the average number indicated by the insurance company (0.55;

SD 1.88) (P =0.021). The overreporting in the cost diary was due to 50% of the patients consulting a physiotherapist, who registered an average of one visit per week.

Cost diary for patients with inflammatory bowel disease (Rosch *et al.*, 2002a; Rosch *et al.*, 2002b)

Cost diary for patient with inflammatory bowel disease measuring disease specific resource utilization and cost was developed and tested in a prospective pilot study in Germany (n=105)

The diary captures visits to health care providers, hospitalizations, medication use, time lost from paid and unpaid work, travel costs and out-of-pocket expenses. The diary was tested over a 4 week follow-up period.

Medical Expenditure Panel Survey (MEPS, http://www.meps.ahrq.gov/mepsweb/survey)

The MEPS is cosponsored by the Agency for Healthcare Research and Quality (AHRQ) and the National Center for Health Statistics. It provides nationally representative estimates of health care use and expenditures for the civilian noninstitutionalized population of the U.S. The MEPS seeks to minimize the effects of longer recall periods (5 months) by asking households to use calendars and keep diaries of all their health care use between interviews and to retrieve medical bills, explanation of benefits forms, and other documents during the actual interviews (Cohen et al. 1996).

Zuvekas and Olin (2009) validated household reports of Medicare-covered services (hospital inpatient, emergency department (ED), and office-based visits in preceding 5 months) against Medicare claims. Participants in MEPS with Medicare coverage during 2001–2003 were matched to their Medicare enrollment and claims data (4,045 person-year observations). In the validation sample, households accurately reported inpatient stays (agreement rate=0.96

k=0.89) and number of nights (Lin’s concordance correlation coefficient = 0.88). Households underreported ED visits by one-third (Lin’s concordance correlation coefficient = 0.51) and office visits by 19 percent (Lin’s concordance correlation coefficient = 0.67).Self-report instruments employed in MEPS are available at http://www.meps.ahrq.gov/mepsweb/survey

3.3. Discussion

The following conclusions can be drawn from the attempt to systematically review published self-report instruments collecting data on health care utilization:

First, despite extensive research on health care utilization per se, information on the development, testing and validation of instruments collecting utilization data by self-report is scarce. Many studies evaluating the accuracy of self-reported health care utilization had to be excluded from the review because they did not provide any information with regard to the self-report tool (number of items, wording, recall period). Better communication of properties of self-report instruments employed in single studies would increase the external validity of research.

Second, it seems rather difficult to validate self-report instruments capturing health care utilization. Most of the identified tools were only partially validated or not validated at all. To be sure, it is extremely difficult to validate some components of health-related resource use against alternative valid data source and for some components of resource use such "gold standard" is hardly available (e.g. for time spent on receiving health care, informal care). The lack of published validated or at least standardized self-report instruments which could be applied across different studies and thus contribute to the comparability of results is somewhat surprising, given the extensive reliance on self-reported health care utilization in national health surveys and epidemiological studies.

Third, it is often difficult to attribute resource utilization to a specific disease. This is particularly true for psychiatric disorders since patients may have physical symptoms caused by the psychiatric illness and may not be able to distinguish between resource utilization caused by psychiatric diseases or by other health problems. Moreover, explicitly asking about resource use caused by mental health problems can adversely affect the validity of obtained data. Nevertheless, almost all identified instruments are disease specific. It is unclear how the attribution problem is resolved. Only Pinto et al (2011) discussed this issue explicitly.

Finally, in line with the general observation with regard to the lack of standardization of self-report instruments, a validated generic questionnaire or at least a standard set of questions on various categories of health care utilization and available for German investigators was not found. Published validated diabetes-specific German questionnaire(s) to collect data on health-related resource use were also not identified.

4. Development of a new questionnaire on health-related resource use and expenditure

In general, two types of questionnaires exist: *generic* questionnaires capture resource use related to health problems in general, whereas *specific* questionnaires explicitly ask about resource utilization and/or expenditure related to a particular illness. However, it is often difficult to attribute resource utilization and cost to a specific disease. This is particularly true for psychiatric disorders since patients may have physical symptoms caused by the psychiatric illness and may not be able to distinguish between resource utilization caused by psychiatric diseases or by other health problems. Moreover, explicitly asking about resource use and/or expenditure caused by mental health problems can adversely affect the validity of obtained data. Hence, a pragmatic approach to handling the issue of cost attribution may be to apply a generic questionnaire collecting data on a broad range of resource use categories and to attempt to determine their attribution afterwards. To enable meaningful analysis under this approach, detailed data on comorbidity (including psychiatric comorbidity) should also be collected.

In this context it was decided to develop a questionnaire collecting data on a range of health-related resource use categories and to complement it by specific questions on diabetes-related resource-use. That is, the objective was to develop a questionnaire with a modular structure allowing for a broader use of the resulting instrument. Such questionnaire can be used both in diabetic patients and – leaving out diabetic-specific profile – also in general population.

The first step in developing this instrument was to identify the potentially relevant generic questions on health care utilisation from the available questionnaires in German language. To this end, we reviewed instruments developed for large scale German health surveys and epidemiologic studies, including (but not limited to) instruments used in DEGS (developed by Robert Koch institute), KORA, Recall, Health monitor “Gesundheitsmonitor” (developed by TNS Health care). Alternative approaches to asking questions covering similar content were grouped together, and a set of questions on general health care utilisation (primary care visits, visits to emergency departments, visits to specialists, hospital stays, and other therapies/paramedical care) was assembled either by adopting wording from those candidate questions directly or by adapting them to fit a question form that seemed to be more appropriate for the new instrument. Specific diabetes-related questions were elaborated in close cooperation with the clinical experts in the field of diabetology from the German Diabetes Centre (Dr. Nanette Schloot) and from the research institute of the Diabetes Academy Mergentheim (Profesor Bernd Kulzer and Dr. Norbert Hermanns).

Particular attention was paid to the development of questions regarding medication use (medication name, strength, prescribed frequency, and duration of use). Items capturing (i) current use of diabetes-specific medication, (2) changes in diabetes-specific medication profile within a defined reference period, i.e. changes with regard to the number of medications taken, the dosage level for one or more medications, and the pharmacologic class of the medications being taken; (3) current use of regularly taken medications for other conditions and (3) occasionally taken medication within a defined reference period were developed (see Attachment I, questions 16-19 and 23-24).

The resulting questionnaire (see Attachment I) collects data on (i) a wide range of health care services utilization during a specified recall period (number of visits to the general practitioner, including home visits of the general practitioner, number of visits to emergency room/departments, number of outpatient visits to various specialists and therapists, utilization of hospital outpatient services, diagnostic tests and procedures carried out ambulatory, hospital inpatient admissions and their duration; (ii) time spent obtaining these healthcare services, (iii) use of diabetes-specific and other medication (iv) out of pocket expenditure on medication; (v) comorbidity (vi) disability days and days off work and (vii) unpaid or paid help received by the patient because of a limited ability to do household chores (the time for which help was needed and corresponding cost if applicable); (viii) some other variables which may be required to analyse the data (e.g. participation in the disease management programmes and employment status).

5. Questionnaire pretest

In a traditional questionnaire pretest questions are usually evaluated using loosely structured respondent debriefings (i.e., asking the respondents whether they had any difficulties in answering the survey items) and/ or interviewer debriefings (i.e., asking the interviewers whether the respondents had any difficulties answering the survey items). Significant limitation of such pretests is that the criteria for evaluation of questions are often not well articulated and the information obtained from debriefings is often unsystematic. Whereas some problems may surely become apparent in the course of a traditional pretest interview, others may require special steps to be detected (Presser *et al.*, 2004). Hence, in the last two decades there has been considerable effort to develop more systematic methods of pretesting survey questions (see. e.g. Prüfer & Rexroth (1996) for an overview). These methods are outlined below.

Behavior coding

Behavior of a respondent and/or interaction between respondent and interviewer is systematically "coded" with respect to several behaviors suggestive of problems with a question. For example: respondent expresses uncertainty; respondent requests clarification; respondent provides inappropriate (uncodeable) answer, interviewer has to use follow up questions (probes) to get an answer, etc. Each time the coder hears evidence of these problems she or he applies that code for the relevant questions, so that at the end of the study aggregate coding summaries over a number of interviews are available and the relative frequency that a question produced a particular code, i.e. a deviation from the "perfect" question-answer process, can be analyzed. The more often deviations occur, the more likely there is a problem with the question. Behavior coding can be done live, but is more often accomplished by a subsequent analysis of recordings (taped recorded or in digitized form).

The strength of behavior coding results is their systematic and quantitative nature allowing comparison across questions and surveys. Yet, behavior coding focuses on identification of *observable* problems defined a-priori and information from behavior coding usually need to be supplemented by cognitive methods in order to identify possible reasons for observed problems and/or to reveal problems not evident in the response behavior such as silent misinterpretation.

Cognitive testing of questions

Cognitive testing is concerned with how people interpret and comprehend questions, recall information, make judgments about how to respond, and provide a response. Cognitive methods enable to explore the processes by which respondents answer questions and to identify errors being introduced into the process. In particular, cognitive testing of questions aim to establish whether respondents (i) can understand the question concept or task, (ii) do so in a consistent way, and in a way the researchers intended, (iii) are able and willing to provide an adequate answer (Willis, 2005). This knowledge can be used to develop better survey questions, thereby improving the reliability and accuracy of survey responses (Harris-Kojetin *et al.*, 1999; Willis, 2005).

Many of the cognitive methods were originally developed by psychologists to investigate how people solve problems or remember things and have been adopted by survey researchers to identify sources of measurement error and to improve the quality of data from self-report. Cognitive testing methods which can be applied to evaluate survey instruments include probing, think aloud interviewing, paraphrasing, card sorts, vignettes, confidence ratings and response latency timing (see, for example, Jobe (2003) for an overview). These methods are increasingly being used routinely to pre-test questionnaires. Many statistical agencies now have cognitive testing facilities or laboratories and complement traditional field tests by pretests using cognitive methods (Collins, 2003).

Procedures for cognitive testing of questions vary greatly. Willis (2005) provides an overview of various ways in which such testing can be carried out, and a discussion on strengths and limitations of the alternative approaches. For all of the approaches, respondents are asked to answer a test question or a series of questions. Then, some researchers have interviewers ask a series of follow-up questions (probes), asking the respondents to explain how each question was understood and how they arrived at the answers they gave. Other researchers have the respondents think out loud, explaining how they came up with their responses, or have the respondents think out loud and follow this activity with a series of follow-up probes. Some researchers carefully script probes for interviewers, while others give interviewers more freedom in what they ask. Some researchers probe each question as soon as it is answered; others let respondents answer several or many questions, and then go back over the questions with their follow-up probes. Some researchers have respondents fill out answers on the paper form or computer, while other researchers prefer to have all test questions administered orally by the interviewer (Harris-Kojetin *et al.*, 1999; Levine *et al.*, 2005). No one approach has been demonstrated to be best (Levine *et al.*, 2005; Willis, 2005). However, there is a growing evidence that only a few cognitive interviews can identify problems with questions that can have major effects on data quality (Forsyth *et al.*, 2004).

The questionnaire on health care utilization and other health-related resource use which is described in the Chapter 3 was pretested by a combination of two established techniques – behavior coding and cognitive testing. In the following, the design and results of the pretesting study are summarized.

5.1. Design of the pretest

Study participants

Responders were recruited from a GP practice in Elsdorf (situated near Cologne) and in an outpatient practices specialized on diabetes treatment in Leverkusen. We aimed to recruit respondents representative of the range of individuals who will be sampled in the future surveys or recruited to RCTs. To this end, so-called “qualitative sampling approach” typical for focus groups and cognitive interviews and aiming to explore the diversity was applied.

Testing procedure

The questionnaire was tested both as self-administered and as an interviewer-administered tool. A standardized behavior coding form (see Attachment II) was employed by an observer while the respondents were completing the questionnaire and during the interviews to register problem indicators for questions under study. The following set of problem indicators was used:

- Request for clarification
- Answer with comments, i.e. answer appears to meet question objective, but comments indicate uncertainty, misunderstanding, etc.
- Inadequate answer, i.e. answer that does not meet question objective
- “Don’t know” answer
- Item non-response/missing.

In order to enable behavior coding in the self-administration group, participants were instructed to report any difficulties or problems with questions while completing the questionnaire. Problem indicators “inadequate answer“ and “item non-response (i.e. missing) were assigned during the follow-up interview and by a subsequent analysis of the filled questionnaires. Retrospective approach to conducting cognitive interviews was used in this group. Once the participant completed the entire questionnaire, the interviewer went back through the questionnaire with the participant and asked scripted follow-up questions (probes) for particular survey questions. In the interviewer-administered group, a concurrent approach was implemented, i.e. the interviewer read the survey questions aloud and probed immediately after the respondent answered a particular question. Concurrent strategy aimed to avoid retrospection problems which might occur when probing is carried out at the end of the questionnaire. However, concurrent probing can influence responses to subsequent questions and it was important to control for this possibility by implementing retrospective probing in the self-administration group.

Interview protocol which included questionnaire items and scripted follow-up probes was used to conduct the interviews. Interviewer was free to ask additional probes as needed, but was expected to ask the scripted probes. Scripted probes were used to (i) provide some standardization of analyses across interviews and to ensure that the survey questions of greatest concern get probed appropriately within the limited cognitive interview time. Two various types of probes were employed:

1. Comprehension probes asked respondents to explain their understanding of a particular concepts or terms.
2. Information retrieval probes asked to explain how they arrived at an answer and to rate the degree of confidence in their answers (confidence rating).

Attachment I contains scripted probes and confidence ratings used for a given question wording. The protocol concluded with a series of general questions allowing the respondent to provide additional feedback about particular items or the questionnaire as a whole.

Interviewer and observer were professional research staff; who received training in cognitive interviewing techniques prior to conducting interviews. Test-interviews supervised by a psychologist were conducted in the diabetes outpatient department of the University clinical center in Düsseldorf. Test interviews were also used to test and modify indicators for behavior coding and to finalize the interview protocol.

Analysis

The interviews were tape recorded (with the permission of the respondents). Two researches (interviewer and observer) independently performed behavior coding from the tape recordings. Behavior coding done during the interviews was also reviewed. Disagreement with regard to behavior coding was solved by consensus. Questions were classified as problematic if 15 % or more of responders had problem(s) with a question, i.e. at least one problem indicator was assigned to the question in 15 % or more of the interviews. Further qualitative analysis of interviews was performed to identify possible reasons for problems suggested by response behavior, to reveal problems not evident from response behavior and to inform revision of questions.

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5.2. Results

We conducted 43 cognitive interviews. Respondents were individuals with diabetes mellitus type1 (n = 10) and type 2 (n = 33). Seventeen of the respondents were males and 26 were females. Respondent age ranged from 21 to 86 years (mean = 60.0). The questionnaire was tested as self-administered and as an interviewer-administered tool in 19 and 24 patients respectively. Some characteristics of respondents are presented in the Table 6.

Table 6: Respondent characteristics

Respondent characteristics	N
Years of schooling	
No schooling	3
≤10 years	27
12-13 years	9
Not specified/ unclear	4
Employment status	
Working full-time	12
Working part-time	5
Unemployed	4
At home	3
Retired	19

Analysis of response behavior

If according to analysis of response behavior more than 15 % of respondents seem to have difficulties in answering a question, the question was classified as problematic. Problematic questions and frequency distribution of various problem indicators are shown in the Table 7. “Item non-response” and “inadequate answer” indicate serious problems, which are likely to influence the quality of collected data. Question 5 (about the number of visits to the general practitioner in the last 6 months), question 7 (about the number visits to specialists in the last 6 months), question 23 (about currently taken regular medication), question 25 (about out of pocket expenditure on medication in the last 6 months), and question 8 (about time spent on receiving health care services in the last 6 months) had particularly high levels of these indicators. Question 5, question 8, question 23 and question 25 also produced a relatively high percentage of “don’t know” answers – 14%, 19%, 12% and 19 % respectively.

If the respondent gave inadequate answer or if item non-response occurred, the interviewer usually reacted with (unscripted) probing. We analyzed responses to the reactive probing and – if the answer was inadequate even after feedback from the interviewer – assigned a code “no improvement by probing” (see the last line in the Table 7). As it can be seen from the Table, reactive probing substantially improved initial results for many questions. Question 7 about visits to specialists is rather typical in this regard. Initially, there were a high proportion of missing answers in a self-administration group and inadequate answers in the interviewer-administered group. Many participants did not give the number of visits in the last 6 months as required by the question, but rather answered with a rate per time period (e.g. 1 visit every 3 months). In such cases probing usually resulted in the adequate answer, that is, a number of visits. However, even after reactive probing many participants were not able to give an adequate answer to the question about frequency of visits to the general practitioner in the last 6 months (26%), question about time spent on receiving healthcare services in the last 6 months (39%), question about regular medication currently taken (35%) and question about out of pocket expenditure on medication in the last 6 months (42%). The ability to correctly recall drug name and strength without reference to written lists, prescriptions or packages appears to be rather poor.

Table 7: Distribution of problem indicator levels for questions, which caused problems to 15 % or more of respondents

Problem indicators	**Question №***											
	5	**6**	**7**	**8**	**9**	**11**	**16**	**17**	**19**	**23**	**24**	**25**
Item non-response/ missing	18	2	10	16	8	2	5	9	7	21	11	14
Inadequate answer	19	14	13	4	3	8	10	3	1	12	3	10
Request for clarification	9	1	7	5	2	1	4	1	1	7	1	10
Answer with comments	8	1	2	10	4	4	5	0	1	3	1	11
Do not know	6	0	2	8	3	0	1	1	0	5	1	8
∑	60	18	34	43	20	15	25	14		48	17	53
No improvement by probing	11	3	5	17	3	1	0	4	1	15	8	18

*See Attachment I for wording of questions

Results of cognitive testing (probing and confidence rating)

Item non response, inadequate answer, or don't know answer may be associated with information retrieval problems. However, verbal reports in response to scripted information retrieval probes asking how the responders arrived at their answers and/or how difficult it was for them to answer and/or how confident they were in their answers were not very informative for the questions 5 and the question 7. Most responders were not able to explain how they arrived at their answer for number of visits to GP and to various specialists in the last 6 months, i.e. whether they counted single visits, make an estimate, etc. Interestingly, when asked if the answer was exact, not very precise, or a rough estimate, many respondents were very confident about their answers even though their response behaviour suggested otherwise.[3] This is illustrated in the Table 8.

For the question 8 about time spent on receiving health care and for the question 25 about out-of-pocket expenditure on medication results of behavior coding were confirmed by probing. Both questions represent a difficult task for responders and 28 % of responders were not confident in their answer, i.e. they told it was a rough estimate.

Table 8: Confidence rating for questions on the number of visits to the GP and to various specialists in the last 6 months: How difficult was it for you to recall the number of visits in the last 6 months? Do you think the number of visits you gave is exact, not very precise or a rough estimate?

Confidence rating	Number of visits to GP	Number of visits to specialists
Exact	25	37
Not very precise	8	0
Rough estimate	7	0
Not conducted	3	6

In sum, the following comprehension problems were identified by scripted and unscripted probing:

- 19 respondents did not distinguish between the general practitioner, internist and diabetologist, and tended to count the visits to these physicians twice, i.e. they first mentioned the visits in response to the question about the visits to the GP, and then mentioned them again in response to the question about visits to the specialist (the

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[3] As already mentioned many participants had difficulties with these questions and additional probing was often needed to obtain the number of visits.

question includes a list of various specialists).

- For some respondents it was not clear that question 7 explicitly asks about the frequency of visits to the specialists working in the ambulatory sector and not in the hospital.
- Most respondents were not able to clearly differentiate between a psychiatrist, a psychotherapist, and a psychologist. 20 participants knew that there is a distinction, but could not correctly explain the difference. Some participants also mentioned neurologist here. 22 respondents did not even make a distinction.
- Some respondents mentioned emergency care obtained in the hospital in response to the question about ambulatory healthcare services provided in hospital, although the question explicitly instructed not to include emergency care.
- Many respondents found the question aimed to capture changes in diabetes-specific therapy (medication, insulin) in the previous 6 months unclear or difficult.
- The term “medication” was not understood consistently by all respondents. Accordingly, some respondents considered only prescription medication, but not over the counter medication when answering the question about their out- of- pocket expenditure on medication

5.3. Modification of the questionnaire

Revision of questions

On the basis of information obtained from cognitive testing the questionnaire was revised (see Attachment III and Attachment IV for the revised version of the questionnaire). Revisions were mainly undertaken to overcome comprehension difficulties revealed by the pretest in order to reduce the number of inconsistent answers across respondents. Some questions were re-ordered, for some questions wording was changed, some questions were split (for example, there are now two separate questions on out of pocket expenditure – one regarding the prescription medication and the other one referring to the over the counter medication) and sometimes additional instructions were introduced.

Mode of questionnaire administration

For many questions additional extensive probing was needed to obtain an adequate answer, which suggests that responders may be unable or unwilling to exert the level of effort needed to provide adequate answer without external assistance. This challenges the possibility to administer questions on health care utilization and other health-related resource use as self-administered items.

Because the questions capturing medication use were proven to be particularly difficult as well as very time consuming, computer assisted version of these questions was developed to make data collection more efficient. The items are displayed to the interviewer on a computer screen (on a laptop), the interviewer reads the questions to the respondent and enters their responses directly to the electronic database. Moreover, if the medication packages are available at the time of the interview the barcodes can be scanned which allows classifying the medications according to the Anatomical Therapeutic Chemical (ATC) Classification System and obviates the need to collect the information on the name, strength and form of the medication. In this case participants only have to report the frequency and duration of administration.

Self-reported comorbidity

As already mentioned above, analysis of health-related resource use often requires a careful case-mix adjustment. Self-reported comorbidity is of critical importance in this regard. During the pre-test it was realized that questions on comorbidity which we included to the initial version of the questionnaire could be insufficient for these purposes. Consequently, initial questions on comorbidity underwent extensive revision based on literature review (see the final questionnaire in the Attachment III).

6. Validity of self-reported health-related resource use

Cognitive interviews can indicate the existence of problems with questions (e.g. difficulties with questions occurring in a particular subgroup or for a particular recall period or with the mode of administration). However, they cannot provide quantitative information on the quality of self-report data. To obtain this type of information, studies comparing self-reported data to data from alternative sources are required. Ideally, the questions should be validated according to a range of criteria (e.g. for different recall periods and modes of administration) and within a variety of populations in order to meaningfully interpret health care utilization reported in single studies and to compare findings across studies.

In the following, (1) a conceptual model of factors which can affect the accuracy of self-reported health care utilization proposed by Bhandari and Wagner (2006) is outlined; (2) the research on the accuracy of self-reported health care utilization is discussed within this framework; (3) design and methods of a questionnaire validation study, which were developed under the consideration of the conceptual model and empirical evidence are outlined.

6.1. Conceptual model

Bhandari and Wagner (2006) developed a conceptual model of the factors affecting the accuracy of self-reported health care utilization. According to this model factors potentially influencing quality of self-reported data, i.e. causing variable error or bias, can be categorized into and modifiable and fixed attributes of data collection process:

- Modifiable attributes of data collection include *type of utilization* (e.g., emergency department visit, inpatient hospitalization, physician visits, medication, etc.), *utilization frequency*, *length of recall time frame* (e.g., 3 months, 6 months or 12 months), *questionnaire design*, i.e. wording, structure and order of items in the questionnaire, and

  mode of data collection (mailed surveys, telephone interviews, in person interviews, Internet-based surveys, diaries).
- Socio-demographic factors represent fixed attributes and capture variance associated with cognitive impairment (e.g., dementia) as well as variance associated with underlying cognitive differences and psychosocial influences on the interpretation of survey questions.

6.2. Empirical evidence

The discussion builds on a review of Bhandari and Wagner (2006) which focused on validity of self-reported ambulatory visits as a measure of resource utilization and a review of Evans and Crawford (1999) which included also other components of health-related resource use such as hospitalisations, medical tests, medication use and lost work days. These reviews have been extended by the consideration of more recent studies.

6.2.1. Type of utilization

Self-report accuracy increases for major and rare events such as hospitalization compared to outpatient visits (Weissman *et al.*, 1996; Ungar and Coyte, 1998; Wolinsky *et al.*, 2007; Roberts *et al.*, 1996). For example, Wolinsky et al. (2007) studied the concordance between self-reported hospitalizations and physician visits in the last 12 months and respective claims data and reported that there were only 11 % divergent cases (N = 4229) on the number of hospital episodes, most of which (79.4%) involved overreporting by respondents. The concordance between the self-reported and claims-based physician visit was markedly lower: weighted $\kappa = 0.351$ for the 14 × 14 comparison of none, 1,…, 12, or ≥13 for physician visits in the last 12 months compared to weighted $\kappa = 0.671$ for the 6 × 6 comparison of none, 1,…, 4, or ≥5 for hospital episodes in the last 12 months. In the validation study of Wallihan et al. (1999) over 60% of patients underestimated their number of ambulatory visits in the past year with 30.9% underestimating use by 4 or more visits.

Hospitalizations with longer lengths of stay are more likely to be remembered than shorter ones (Norrish *et al.*, 1994; Clark *et al.*, 1996), although they were also associated with less accurate reports on the length of stay (Clark *et al.*, 1996).

There is evidence that stigmatized care such as mental health visits are underreported (Hennessy and Reed, 1992; Clark *et al.*, 1996; Spector and Bedell, 1982). Though counterintuitive to the social undesirability problem, some studies have shown overreporting of psychiatric visits (Kashner *et al.*, 1999; Taube *et al.*, 1986; Golding *et al.*, 1988).

The accuracy of self-reported medication use has been investigated in several studies, using provider records and/ or pharmacy records as the “gold standard” (see e.g. (Lewis *et al.*, 2006; Caskie *et al.*, 2006; Nielsen *et al.*, 2008; Haukka *et al.*, 2007; Solomon *et al.*, 2007; Klungel *et al.*, 2000; West *et al.*, 1995; al Mahdy and Seymour, 1990; Van den Brandt *et al.*, 1991; Paganini-Hill and Ross, 1982). According to these studies, accuracy of recall on medications varies depending on therapeutic class, type of use, i.e. used on a regular basis or as needed and duration of use. A population-based American study (n=1,430) compared current self-reported medication use with the pharmacy prescription records and found that the agreement between self-reported medicine use and pharmacy records was better for medicines used for serious conditions or on a regular basis (Caskie *et al.*, 2006). Nielsen et al. (2008) linked self-report data on current medication use from the nationally representative Danish health survey conducted in 2000 (n=16,688) to national prescription records covering 1999-2000. It was checked whether the individual had collected at least one prescription of the analyzed ATC group during the 90 days prior to the survey interview. Agreement between the two sources was analyzed using the kappa statistic. The lowest kappa was 0.39 (95% CI=0.34–0.44) and applied to hypnotics and sedatives, whereas best agreement was found for insulins and analogs and oral drugs to lower blood glucose (0.82 [95% CI=0.77–0.87 and 0.78–0.86, respectively]). Therapeutic groups with a high probability of chronic use showed good to very good agreement (kappa >0.6). For therapeutic groups normally used as needed, agreement was fair to good.

Revicki et al. (1994) estimated the level of agreement of telephone-reported work/total leave days lost and time sheet records in the US during a 1- and 3-month period. The research revealed that the reported versus actual sick days differed by only 0.20 days at 3 months. The interclass correlation coefficient for sick days at 3 months was 0.86, demonstrating nearly complete agreement. Merkesdal et al. (2005) also showed a strong correlation (r = 0.83) between patient reported sick days in the last 3 months and health insurance data.

6.2.2. Utilization frequency

Many studies consistently reported an association between increased frequency of health services utilisation and underreporting (e.g. (Ritter *et al.*, 2001; Wallihan *et al.*, 1999; Kashner *et al.*, 1999; Jobe *et al.*, 1990; Roberts *et al.*, 1996; Weissman *et al.*, 1996; Schmitz *et al.*, 2002; Bellon *et al.*, 2000; Glandon *et al.*, 1992). For example, in a study of Kashner et al. (1999) precision of self-report[4] did not exceed 10 % but increased to 37 % - 41 % when the sample excluded the top 20 % of ambulatory care users. Roberts et al. (1996) showed underreporting at higher numbers of ambulatory physician visits, with twice as many having had 6 to 10 or ≥11 visits in the past year based on the medical records compared to self-report ($p < 0.001$). Wallihan et al. (1999) modeled under-estimation of total number of ambulatory care visits (underestimate > 2 visits) using logistic regression. The volume of ambulatory visits was significant correlate of underestimation (OR =1.29, CI = 1.18 –1.40).

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[4] Precision of self-reported outpatient visits in the last 6 months was measured as the percent of record-based variance that could be explained by patient-based estimates. Precision was calculated as an R^2 to a fitted regression line where the number of record-based visits (y-axis) was plotted for each study patient against the number of self-reported visits (x-axis).

Respondents may use different cognitive processes when recalling frequent events than when remembering less common events (Means and Loftus, 1991; Blair and Burton, 1987; Jobe *et al.*, 1990). Means and Loftus (1991) found that memory for medical visits became generic (i.e., respondents could only remember a typical visit) when five or more visits occurred for a chronic condition, with respondents being unable to recall the individual visits.

Klungel et al 2000) provided evidence that accuracy of recall on medication reduced with the number of drugs used.

6.2.3. Recall time frame

Table 4 summarizes the evidence with regard to over-, concordant-, and underreporting of physician visits for recall periods of different length from studies where these data were reported. Inaccuracy of self-report for physician visits increases for longer recall periods, with underreporting being a substantially more frequent problem at 12 months than overreporting (see Table 4). Telescoping and memory decay are two problems related to the recall time frame which affect the accuracy of recall. Telescoping exists when the person lengthens the recall period few weeks or even months beyond a time horizon in question and these events are “telescoped” into the recall time frame. Alternatively, visits within the time frame may be reverse telescoped to outside the recall period (Bhandari and Wagner, 2006). Forward or backward telescoping, i.e. incorrectly placing an event within or outside of the recall period can result in either over- or underreporting. The effect of telescoping was studied by Carsjo et al. (1994). On the basis of administrative data they identified physician visits which were likely to be subject to telescoping by the respondent, i.e. whose location in time bordered on the recall period (within 4 weeks before and after the end of the 3-month recall period) and analyzed changes in overall agreement between self-reported physician visits and administrative data extending the recall period week by week in both directions, i.e., by ± 1 week, ± 2 weeks etc. up to ± 4 weeks. Overall agreement changed from 80 % with a recall period of 3 months to 86 percent with a recall period of 3 months ± 2 weeks to 89 percent with a recall period of 3 months ± 4 weeks. If one assumes that all individuals who made physician visits within ± 3 weeks of the recall period but failed to report this correctly in the interview did so because of forward or backward telescoping, the telescope effect would account for 33 % of the overreporting and 51 % of the underreporting among the respondents. However, in the case of underreporting it is also possible that some underreported visits were not telescoped backward, but simply forgotten since they took place a relatively long time before the interview (Carsjo *et al.*, 1994).

Available evidence suggests that self-reported hospital episodes remain valid for recall periods up to 12-month (see e.g. (Wolinsky *et al.*, 2007; Petrou *et al.*, 2002; Roberts *et al.*, 1996).

Bellon et al. (2000) and Petrou et al. (2002) examined the effect of the length of recall period on the validity of self-reported health care utilization by within-subject comparison, i.e. participants were asked to report the utilization frequency for recall periods of different length - 2 weeks, 3 months, 6 months, and 12 months preceding the interview (Bellon *et al.*, 2000); 4 months and 8 months (Petrou *et al.*, 2002). In the study of Bellon et al (2000) absolute concordance between self-reported and recorded utilization decreased as time interval lengthened. Yet, the authors argued that in relative terms (when different maximum variability in each period is taken into account), the validity of self-reported utilization did not decrease with time, i.e. all periods yielded similar corrected Spearman correlation coefficients obtained between the number of self-reported and recorded visits. In multiple regression analyses the actual number of visits was the main factor associated with both underreporting and overreporting. Petrou et al. (2000) reported significant differences between the medically recorded and self-reported distributions of general practitioner visits for both recall periods ($p<0.001$). There were no significant differences between the medically recorded and self-reported distributions of other health service encounters. Application of a multivariate linear regression model to the general practitioner data showed that the absolute number of recorded general practitioner visits was significantly associated with underreporting for both recall periods, with the magnitude of the coefficient increasing as the length of the recall period increases.

The evidence for the use of patient recall of days off work is limited. Identified evidence suggests that accuracy of recall is quite high for the medium term (up to 6 months). Research in this area needs to be expanded to examine longer recall periods.

6.2.4. Mode of data collection

Self-reported data can be collected using 4 main methods: (1) face-to-face interviews; (2) telephone interviews; (3) self-administered questionnaire; (4) diaries. These methods can also be combined, for example diary supplemented with telephone contact, or a diary followed by a face-to-face interview. Modes of data collection by questionnaire differ in several ways at different level (Bowling, 2005):

- regarding to the method of initially contacting the respondents, ranging from an initial letter of introduction giving notice of the study, personal face-to-face, email or telephone contact at the same time as the provision of, or administration of the questionnaire, depending on its mode of administration;
- regarding the medium of delivering the questionnaire to respondents: in person, by telephone, by post or electronically (e.g. by email).
- regarding the actual administration of the questions.

(a) verbal – interviewers, face-to-face, using traditional paper and pencil interview (PAPI) questionnaires;

(b) verbal – interviewers, face-to-face, using computer assisted personal interviewing methods via personal computer (pc) or laptop pc questionnaire programs (CAPI);

(c) verbal – interviewers, by telephone, using paper or electronic computer assisted questionnaires (CATI).

(d) traditional paper and pencil self-administration 'interview' methods (PAPI) by post, or handing paper questionnaires to people in person and asking them to complete them by hand and return them to the researcher;

(e) computer-assisted (electronic) self-administration 'interview' methods (CASI) by automated electronic, including audio computer-assisted, methods;

(f) self-administration via interactive voice response methods with automated computer-assisted telephone programs (ACASI).

Summary of potential effects of mode of questionnaire administration based on a literature review conducted by Bowling (2005) is presented in the Table 9. However, she noted that this should be interpreted with caution, given that the literature is not always consistent and rarely based on experimental designs.

Table 9: Summary of potential biases by mode of questionnaire administration

Potential for	Face-to face interview	Telephone interview	Self-administered, postal	Self-administered, electronic
More complete population coverage for sampling (reduces sampling error)	high	low	high	low
Non-response bias	low	high	medium-high	high
Item non-response	low	high	high	high
Recall bias	low	low	high	high
Social desirability bias	high	high	low	low

Adapted from Bowling (2005)

For example, Gundgaard et al. (2008) compared magnitude of non-response bias in two types of health interview surveys. The surveys were (1) a national personal interview survey of 22 484 Danes (2) a telephone interview survey of 5000 Danes living in Funen County. The surveys produced the same pattern of non-response: response rates for the interview and telephone surveys were 75 and 69%, respectively. This finding contradicts the conclusions of Bowling (2005). However, it is difficult to make definitive conclusions based on comparison of different samples since factors other than mode-of administration might also influence the response rates.

Etter and Perneger (1997) explored the possible non-response bias in a mailed health survey. Persons who returned and those who did not return the questionnaire were compared using health insurance data, which indicated their age, sex, and health care expenditures in the previous year. Participants were members of health insurance plans in Geneva, Switzerland, 19-45 years old (n = 1822). Respondents (n = 1424) and non-respondents (n = 398) were of similar age and sex. The proportion of persons who had health care expenditures > 0 (SFr) was higher among respondents (75%) than among non-respondents (69%, p = 0.03). The authors concluded that low response rates to mailed health surveys may result in overestimating the utilization of health services.

Reijneveld and Stronks (1999) examined the impact of response-bias on estimates of health care utilization using administrative data on use of health care. Data on health care utilization were extracted from a health insurance register and linked to respondents (2,934; 62.7%) and non-respondents (1,744) in a personal health interview survey among low income residents in Amsterdam, the Netherlands. They found that estimates of health care utilization (prescription drugs, specialist medical care, paramedical care, dental care and medical aids) are higher if based on respondents only, than if they are based on the entire target sample. The study of Goyder and Botha (2001) linking postal questionnaires and medical records, showed that non-respondents were less likely to have attended a hospital diabetes clinic (38% vs 45%) and much less likely to have had a diabetes review in general practice (11% vs 26%). An analysis based on questionnaire respondents would therefore overestimate health service use (the proportion receiving routine reviews in general practice).

Interviews were shown to maximize data completeness for self-reported medication compared to self-administered questionnaires (West, 1997).

There seem to be no consensus with regard to influence of administration mode on the accuracy of recall. In interviews, an interviewer can probe to elicit relevant information, and utilize a range of techniques to prompt memory which is not possible in self-administration settings. Yet, interviewers must be cautioned not to introduce bias by probing (Evans and Crawford, 1999). Under self-administered conditions respondents themselves can consult diaries or other information sources to aid recall. Moreover, Schwarz et al. (1991) argued that – assuming sufficient motivation – respondents may be expected to engage in more extended retrieval efforts under self-administered than under face-to-face conditions. He also argued that under the increased time pressure of telephone interview conditions respondents are likely to truncate the information retrieval process most quickly. Accordingly, reliance on easily accessible information and the use of heuristic judgmental strategies may be expected to be most pronounced under the latter mode of data collection, which has also been found to result in less accurate recall of public events (Schwarz *et al.*, 1991). Norrish et al. (1994) speculated that underreporting of hospitalizations in their study may be due, in part, to the use of telephone interviews versus in-person interviews. Empirical evidence in is scarce. In the Medical Economics Survey-Methods Study (Yaffe *et al.*, 1978) in-person contact resulted in significantly better reporting compared with telephone contact in the Baltimore area, but no difference was found in more rural Washington country.

From the theoretical perspective diaries represent a prospective data collection method and might improve accuracy of self-report by avoiding or reducing recall bias. Yet, two important considerations when using diary cards are whether patients fill them in at the time of receiving care or whether they wait to fill them in immediately prior to the return date. These design aspects will affect the validity of the method. Verbrugge (1980) conducted a literature review of the use of health diaries with particular reference to their reliability, efficiency, validity and cost. He concluded that diaries produced more accurate content and better data quality than questionnaires. A disadvantage of using diary cards is that patients may fail to complete them, although this could be overcome through reminder telephone calls (Mauskopf *et al.*, 1996). The costs of data collection by diary cards may therefore increase if researchers are required to motivate patients to complete them and to monitor their completion. Diary cards may also have additional data entry and analysis requirements. Patient cooperation with diary filling has been found to be good, although sensitization may occur initially, when completing a diary stimulates patients to take more interest in their condition, thereby recording more resource use (Verbrugge, 1980). Patient fatigue may also occur and it has been shown that, in studies conducted over 1–2 months, a reduction in motivation may occur and hence the thoroughness of the reporting is reduced (Verbrugge, 1980). Diary cards may provide more accurate data on some patients but a potential drawback could be missing data for others (Weinberger *et al.*, 1993).

Optimal mode of administration likely depends on the type of utilization. Respondents asked to self-report on a stigmatized illness may be more willing to provide information on a mailed or internet survey, thus leading naturally to the use of mixed modes. Respondents have been found to be most likely to provide socially desirable responses under face-to-face interview conditions, and least likely to do so under self-administered conditions, whereas the data bearing on telephone interview conditions are mixed (Schwarz *et al.*, 1991; Bowling, 2005).

6.2.5. Questionnaire design

Gama et al. (2009) reviewed systematically the published evidence regarding the effect of questionnaire design on the recall of pharmacological treatments. The number of studies specifically addressing the effect of questionnaire design on the recall of pharmacological treatments was low (n=8) and with a substantial heterogeneity in the methodological approaches, populations studied, drugs evaluated, and in presentation of results. Despite the difficulties in comparing directly the studies reviewed, most of them concluded that questions involving indication for use and drug-specific questions increased the prevalence estimates for drug use compared to an open-ended question. For example, according to a study conducted by Klungel et el. (2000) sensitivity of recall was much better for questions on use of drugs for specific indications (thromboembolic diseases, hypertension, hypercholesterolemia, diabetes, contraception) than for the open-ended question to assess drug use for any other condition (88% and 41% respectively). This association was consistent after stratification for other factors that were associated with recall sensitivity (educational level, self-reported-health status of the respondent, duration of drug use). However, the higher sensitivity of recall could be due to the type of drug that was asked for in these questions.

One form of bias which might be caused by questionnaire design is attenuation: the systematic reduction of reported symptoms or events over time, either from one administration to the next, or within the same administration. In particular, respondents might learn to avoid the burden of followup questions (branch questions) by responding negatively to stem questions; accordingly, survey responses in the latter sections of a long instrument are biased towards underreporting.

Attenuation resulting from stem-and-branch structure can be mitigated by placing all stem-questions before any branch questions are presented (see e.g.(Kessler and Ustun, 2004). Duan et al. (2007) conducted a randomized trial to assess the presence and magnitude of attenuation in the reported service use. They randomized respondents to two versions of the survey instrument, so that responses to service use questions presented in a stem-and-branch format can be compared to responses to an ensemble format with the stem-questions for service use placed near the beginning of the survey. Higher service use rates were reported with the latter format for all service use measures; odds ratios range from 1.41 to 3.10, all p-values <.001.

6.2.6. Memory aids and probes

The use of probes is supported by Kashner et al. (1999), who found a statistically significant increase in the number of visits reported when they probed during in-person interviews (4.9 visits on average without probing versus 9.5 visits on average after probing). Kashner et al. (1999) used probes to identify the location of care, whether the care was psychiatric or medical, and visits to each provider. The authors concluded that “interview probing helped to reduce the risk of under-reporting actual episodes of care” (Kashner *et al.*, 1999). Probing seemed to be especially and significantly beneficial for those respondents who reported no visits before they were probed and was also beneficial (but not significant) for those patients who had high levels of utilization (8-20 visits). Finally, research suggests that accuracy can be improved by using a two–time frame method. Loftus et al. (1992) tested the difference between asking about utilization during the past 2 months and then a following question about utilization during the past 6 months (2-6 approach). This was compared with a 6-2 approach, asking the 6-month utilization question first. The 6-2 approach was more accurate. Loftus and colleagues (1992) contended that using a 6-2 approach will decrease overestimation of specific procedures in comparison to a 2-6 approach. One possible explanation for the increased accuracy of a two–time frame method is that this line of questioning – starting with the longer period and then focusing on a more recent period – indicates to the participant the greater need for a more precise response in the more recent period.

In the study by Kimmel et al. (2003) the utilization of pictures or lists of medicines after an indication-oriented question, resulted in 6.3% of enhanced drug recall

Diaries can be used as a memory aid for participants of RCTs or cohort studies in order to improve recall of events and resource-use at completion of the follow-up questionnaire (Cooper *et al.*, 2003; Cohen *et al.*, 1996). For example, Medical Expenditure Panel Survey (MEPS) seeks to minimize the recall bias by asking households to keep diaries of all their health care use between interviews.

6.2.7. Socio-demographic factors

Analyses of the relationship between patient demographics (age, education, ethnicity, gender, health status, and socioeconomic status) and the accuracy of self-report has produced mixed results. A number of studies have found no relationship between demographics and self-report accuracy (e.g. (Marshall *et al.*, 2003; Ritter *et al.*, 2001; Reijneveld and Stronks, 2001; Reijneveld, 2000; Weissman *et al.*, 1996; Norrish *et al.*, 1994). For example Reijneveld and Stronks (2001) compared the concordance of self-reported and registered hospitalizations (recall period one year, n = 1277), utilization of physiotherapy (recall period one year, n = 1302) and use of prescription drugs (recall period 3 months, n = 899) by socioeconomic group (educational level, income, occupational status)[5] and found no systematic trend in concordance by higher socioeconomic status.

When researchers reported significant associations, age was the most consistent demographic factor associated with self-report inaccuracy (e.g. (Roberts *et al.*, 1996; Raina *et al.*, 2002; Wallihan *et al.*, 1999; Bellon *et al.*, 2000; Mathiowetz and Dipko, 2000). Older age was generally associated with underreporting. Cleary and Jette (1984) examined the extent to which reporting error biased models of utilization and found, for example, that age, number of chronic health problems, and psychological distress influenced reported use of physician services but not actual utilization. The conclusion from this study was that certain patient characteristics can seriously bias models of utilization based on self-reports and that actual records should be used whenever possible. Glandon, Counte, and Tancredi (1992) have specifically studied the validity of self-reported physician utilization among elderly persons (62+ years). The recall period in their study was 6 months. The discrepancy between self-reports and archival information on physician utilization was examined in relation to health status and sociodemographic variables. Multivariate analyses indicated that underreporting and proportional reporting error were greater for those elderly persons with higher levels of utilization, whereas elderly persons in poor health tended to overreport physician visits. They concluded that reporting error may consequently bias models of reported utilization models toward an overestimation of the relationship between health status and utilization. In the study of Wolinsky et al. underreporting of ambulatory care varied by income, education, health status, and race/ethnicity, but much of this variation, while statistically significant, was small in magnitude relative to the overall gap in reporting. That is, underreporting affected all groups to a substantial degree and relative bias between groups was small.

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[5] Data came from a face-to-face health interview survey in Amsterdam and a health insurance register, and were limited to native Dutch and lower and middle income groups.

Table 10: **Summary of validation studies on self-report of physician visits**

% of participants underreopting, correctly reporting or overreporting the number of ambulatory visits for different recall periods

Authors	**Method of self-report**	**Recall time (months)**	**Under-report**	**Agree-ment**	**Over-report**	**Sample size**	**Age range**	**Country**
Schmitz, Russell, and Cutrona (2002)	PQ	1	17	43	40	215	65+	USA
Carsjo, Thorslund, and Warneryd (1994)	I	3	16	61	23	167	75-84	Sweden
Carsjo, Thorslund, and Warneryd (1994)	I	3	21	59	20	264	84+	Sweden
Petrou et al. (2002)	I	4	57	29	14	82	NA	UK
Glandon, Counte, and Tancredi (1992)	I	6	44	28	28	227	62-93	USA
Ungar and Coyte (1998)	T	6	16	67	16	83	18+	Ontario
Bellon et al. (2000)	I	6	30	30	40	589	14+	Spain
Cronan and Walen (2002)	D+I	6	68	18	14	213	60+	USA

Petrou et al. (2002)	I	8	58	28	14	82	NAb	UK
Roberts et al. (1996)	SQ	12	51	30	20	490	40-79	USA
Wallihan, Stump, and Callahan (1999)	T	12	62	12	26	385	60+	USA
Bellon et al. (2000)	I	12	38	17	45	589	14+	Spain
Wolinsky et al 2007	I	12	53	15	32	4182	70+	USA
Cleary & Jette (1984)	I	12	35	38	27	908	18-89	USA
Turkat (1982)	I	18	5	35	60	20	21-79	USA

***D** = diary; **I** = interview; **PQ** = postal questionnaire; **SQ** = self-administered questionnaire; **T** = telephone

Adapted and extended based on Bhandari A, Wagner (2006)

6.2.8. Summary of empirical evidence and implications for further research

The research conducted so far has mainly focused on accuracy of self-reported in-patient care and physician visits as well as medication use. Few validation studies have included utilization of other types of health care services and days of work lost. Summing up, the accuracy of self-report varies strongly across different types of resource use and is a function of recall period and frequency of use, whereas the latter two factors may be interrelated. In general, underreporting, in particular of outpatient consultations and medications, appears to be the most common problem of self-reported resource use. Underreporting seems to increase with the number of visits and length of recall period. However, comparisons across studies are difficult because of substantial heterogeneity of populations studied, measurement methods (recall period, mode of administration), validation approaches ("gold standard" used, statistical analysis of agreement). Different measures of accuracy (e.g. Kappa, percentage agreement, percentage underreporting, percentage overreporting) were used and reported. Definitions of level of agreement differed across studies: for example, some researchers judged the self-report accurate only if it matched with the other data source perfectly, while others judged the self-report data accurate even if there were small differences (e.g., ± 2 visits). Often level of agreement and magnitude of disagreement were not reported at all.

There is a growing consensus among researchers in the field that the accuracy of self-reported information is affected mainly by the pattern of utilization and the nature of information requested (type, frequency and salience of resource use, recall period) rather than by respondent-specific attributes. Respondent characteristics such as age and health status may have some independent effects on reporting accuracy, but often they can be seen as determinants of utilization patterns, which in turn determine reporting error and bias.

Most identified validation studies are characterized by non-experimental designs. Consequently, the influence of modifiable attributes of data collection (e.g. recall period, mode of data collection, questionnaire design) on accuracy of self-report can only be analysed by comparison of different samples. See Table 10 for an attempt to analyse the influence of different recall periods on accuracy of self-reported physician visits.

Taking into consideration that methods of data collection (e.g. data collection interval, mode of administration) differ substantially with regard to their cost, more experimental studies are needed to better quantify the benefits of various methods and to further standardize the questions on health-related resource use and expenditure. To this end, we decided to validate questions on health-related resource use which we developed for two different recall periods applying an experimental design. The design and methods of this validation study which is currently being carried out are described below.

6.3. Design and methods of the questionnaire validation study

Study objectives

Primary objectives are:

(1) to evaluate the agreement between self-reported health-related resource use obtained by means of the questionnaire which we developed and tested and corresponding data available from provider and/ or health insurance records for two different recall periods;

(2) to evaluate the agreement between cost estimates based on self-reported resource use and cost data available from health insurance records;

Secondary objectives are:

(1) to investigate determinants of reporting error, and to consider the effects of reporting error on utilization and cost estimates obtained from self-report;

(2) to examine the discrepancies between self-reported, prescribed (recorded in provider records) and acquired medication (recorded in health insurance claims);

(3) to determine the agreement between self-reported and objective morbidity data to inform the further development of the self-report morbidity questionnaire (see Attachment III)

Study sample and design

Patients with diabetes are recruited in an outpatient clinical centre specialising on diabetes treatment ("Diabetesschwerpunktpraxis") in Leverkusen. Since this is a validation exercise, the non-random sampling procedure is used. All patients who give informed consent to use their medical and health insurance records and are members of a particular SHI (BKK pronova) are included into the study. BKK pronova covers about 60% of patients in the cooperating practices and gave consent to participate in the study. Excluded are patients with poor command of German language.

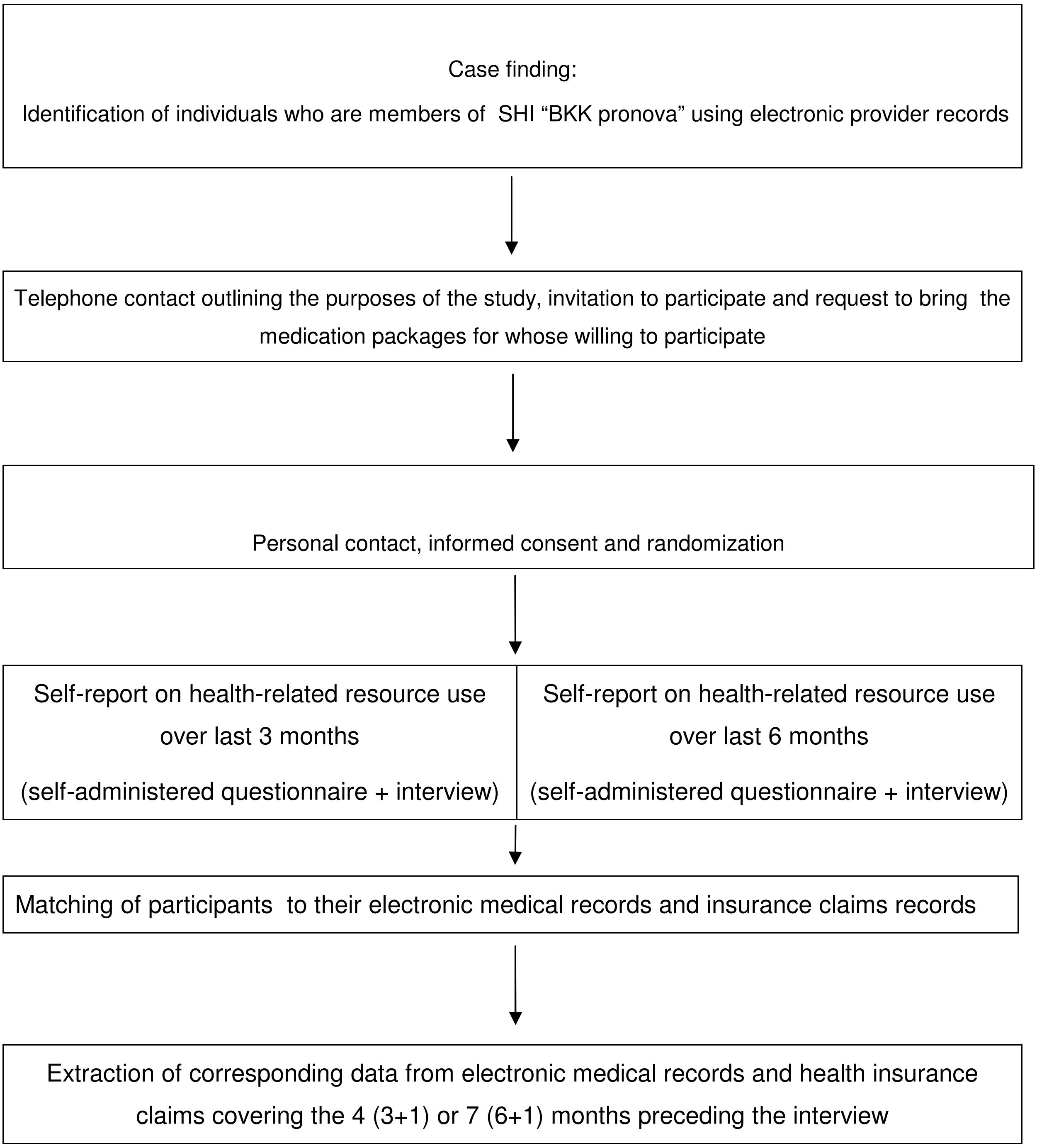
Potential participants are identified using electronic record system of the cooperating outpatient clinical centre in Leverkusen. The record system contains information on insurance status of patients. Patients who are members of BKK Health Insurance Company are contacted by telephone and invited to participate in the study. Telephone contact is also used to exclude patients with poor command of German language. Patients willing to participate are requested to bring their medication packages to their next scheduled appointment in the clinical centre.

To examine the influence of the length of recall period on the accuracy of self-reported data, the patients who give informed consent to participate in the study are randomly assigned to two groups of equal size n. Each group obtains a questionnaire on health-related resource use and expenditure referring to the previous 3 or 6 months respectively.

To validate the resource use and expenditure questionnaire the agreement between utilization reported by the study participants and corresponding utilization data available from medical records of outpatient clinical centre specializing on diabetes treatment and/ or health insurance claims will be examined.

The agreement will be determined for various resource use categories (primary care visits, visits to emergency departments, visits to specialists, hospital stays, medication, and days off work).

Figure 2: Schematic representation of the study design



Case finding:
Identification of individuals who are members of SHI “BKK pronova” using electronic provider records

Telephone contact outlining the purposes of the study, invitation to participate and request to bring the medication packages for whose willing to participate

Personal contact, informed consent and randomization

Self-report on health-related resource use over last 3 months
(self-administered questionnaire + interview)

Self-report on health-related resource use over last 6 months
(self-administered questionnaire + interview)

Matching of participants to their electronic medical records and insurance claims records

Extraction of corresponding data from electronic medical records and health insurance claims covering the 4 (3+1) or 7 (6+1) months preceding the interview

Sample size calculation

Since one of the main objectives of the study is to examine the influence of the length of recall period on the validity of self-report, this aspect was considered for the sample size calculation. We intend to demonstrate that in each group (both versions of the questionnaire: recall period 3 or 6 months) the proportion p of persons with "high agreement" between self-reported and health insurance data is at least 70%. To test the hypothesis H0: $p \leq 70\%$ vs. K: $p > 70\%$ one-sided binomial tests will be performed. It should be guaranteed that the probability of rejecting a true hypothesis at least for one of the groups is less than 5%. Thus, the level of both tests has to be adjusted for multiplicity and is set to 2,5%. In order to ensure that at least one of the tests rejects the corresponding hypothesis with probability of at least 95%, if the true proportion p does not fall below 80%, a sample size of $n = 245$ per group is required. Thus, an overall sample of 490 participants will be recruited.

For each of the tests two conclusions can be made: If the test rejects the hypothesis H0 then the agreement between the self-reported and “true” utilization is high in more than 70% of the persons in the corresponding subset of the investigated population. If the test retains the hypothesis H0 then the agreement of less than 80% of the persons in the corresponding subset of the investigated population is high. For both statements the probability of error is not larger than 5%. If both hypotheses can be rejected, the multiplicity adjustment of the tests allows to combine both test results and with confidence of at least 95% it can be concluded that in both groups more than 70% of the persons have a high agreement between self-reported and health insurance data.

Data collection

Patient recollections of the number of contacts with their general practitioner, including home visits; attendances at accident and emergency rooms/departments; outpatient visits to various medical specialists; outpatient visits to various therapists; hospital outpatient visits; diagnostic tests and procedures carried out ambulatory; hospital inpatient admissions and their duration and days off work are collected by means of self-administered questionnaire which is presented in Attachment III). Upon completion of the self-administered questionnaire participants undergo an interview which allows asking follow up questions to reduce item non-response.

Medication

Information on medication use is collected during the computer assisted interview which was described in more detail in the section 2.

The questionnaire also includes questions on health status and socio-demographic factors:

- *Morbidity:* the number of chronic illnesses reported by the respondent based on a list of chronic conditions. For each disease mentioned, respondents are asked whether the diagnosis was confirmed by a medical professional, whether they have been treated for them in the previous year and whether they experience activity limitations due to the disorder (see Attachment III);
- Number of *disability days* during the last 4 weeks;
- Health-related quality of life will be assessed by the EuroQol (EQ-5D) questionnaire. EQ-5D is a short generic validated and widely used questionnaire for measurement of subjective health. It consists of two parts: five questions relating to distinct dimensions of a patient's functional capacity (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) on each of which 3 responses are possible, and a visual analogue scale (VAS) asking the individual to indicate a self-rating of their current health state (Brooks, 1996);
- *Perceived health* is also assessed with a 5-point Likert-type item categorizing the patient's general health as excellent, very good, good, fair, or poor;
- The *Patient Health Questionnaire* (PHQ-9) is used to screen for depressive symptoms. This questionnaire provides major and minor (subthreshold) depression diagnoses according to Diagnostic and Statistical Manual, 4th Edition (DSM-IV) criteria and a continuous severity score. The PHQ-9 diagnosis has high agreement with a major depression diagnosis based on structured interview (Kroenke *et al.*, 2001). Several studies have used the PHQ-9 to assess depression in diabetes, for example (Simon *et al.*, 2005).
- Basic socio-demographic data will be collected: date of birth, gender, nationality, country of birth, education level, marital status, employment status, and income.

Health insurance records

While not an absolute gold standard, the SHI claims represent the most complete record of the various services provided to the study participants during the 3 or 6 months preceding the interview. Utilisation measures identical to those collected in the questionnaire will be constructed to validate self-reported utilisation. Yet, physician visits that are part of a bundle of services for which the physician receives a single payment (flat or global fee) such as for example regular visits to the general practitioner cannot be traced in health insurance files. Hence, in order to overcome this limitation of the health insurance data and to validate patient self-reports on ambulatory visits patient-reports will be linked to data from provider records, since they contain information on single visits and are thus more suitable for this purpose.

Provider records

Information on outpatient appointments, prescriptions and diagnoses will be abstracted from electronic medical records.

Statistical analysis

First, differences between self-reported and recorded utilization will be calculated at the individual level and the rate of underreporting (difference score < 0), accurate reporting, i.e. agreement (difference score = 0) and overreporting (difference score >0) of resource utilization will be estimated for each type of resource use (outpatient visits, hospital stays, prescribed medications, days off work) and for each recall period. One-sided binomial tests will be used to prove if the proportion of individuals with accurate reporting (agreement) exceeds the specified lower threshold of 70%. For the number of hospital episodes and emergency visits agreement is defined as "1" if the self-reported number matches with the insurance records perfectly and "0" otherwise. For ambulatory visits the proportion of absolute agreement will be estimated and sensitivity analyses using 3 bandwidth criteria (±1 or more visits, ±2 or more visits, and ±3 or more visits) for accurate-reporting will be conducted as well. In sensitivity analyses to explore the possible effect of telescoping we will lengthen/shorten the look-back period by 1 month.

Multivariable multinomial logistic regression will be applied to examine the factors (frequency of service utilization, respondent's age, gender, depression status, education and income) associated with overreporting, underreporting, and accurate-reporting (Concato *et al.*, 1993).

Second, to facilitate comparison of our results with other studies, frequently used measures of concordance between the two data collection methods will be estimated:

- Descriptive statistics of self-reported utilization and utilization recorded in medical records and/ or health insurance claims; mean differences and 95% confidence intervals, indicating systematic bias will be reported for each type of resource use for each recall period;
- Beyond chance (chance corrected) agreement will be assessed using Cohen's kappa statistic. Concordance on hospital episodes and physician visits will be evaluated using simple and weighted kappa (κ) statistics, as appropriate for 2 × 2 and larger (i.e., N × N) tables, respectively (Landis and Koch, 1977). A weighted Kappa statistic will be computed with weights suggested by Maclure and Willett (1987) for analysis of ordinal data; the square of the deviation of a pair of observations from exact agreement will be used as the weight for each disagreement. For the hospital visits weighted κ for the 6 × 6 comparison of none, 1,…, 4, or ≥5 will be estimated. For ambulatory visits weighted κ for the 14 × 14 comparison of none, 1,…, 12, or ≥13 will be estimated.

- The level of agreement for the continuous utilization measures will also be estimated with intraclass correlation coefficients (ICC) based on 2-way mixed models (Shrout and Fleiss, 1979) and with Lin's concordance measure, which is scaled from -1 for perfect disagreement to 1 for perfect agreement (Lin, 1989).
- To assess agreement with regard to costs mean differences (bias) and intraclass correlation coefficients (ICC) will be calculated.

For medication use agreement will be assessed by determining whether self-report and claims data identified drugs in the same ATC class. The observed agreement (proportion of participants for whom claims data and self-report data agree) will be defined for each drug category. Bias- and prevalence-adjusted κ coefficients (BPAC) and their 95% confidence intervals will be calculated because κ is affected in complex ways by the existence of bias between methods and by the distributions of data across the groupings that are used (Byrt *et al.*, 1993). Several different time frames will be used to identify medication use from health insurance claims.

Compared to studies previously reported in the literature, there are several advantages of the presented validation study. First, the study aims to validate a comprehensive questionnaire collecting data on a wide range of different health care services and medication use, whereas previous validation studies focused mainly on a particular type of health care utilization, for example ambulatory visits and/or hospital episodes or medication use. Second, experimental design is applied to examine influence of different length of recall on the accuracy of self-reported health care utilization. Third, two alternative data sources (provider records and health insurance claims) will be used to validate self-reports.

7. Discussion and outlook

Collecting self-report data is based on a challenging cognitive process: respondents must comprehend a question, engage in memory retrieval, form a judgment, and create an answer. Research on validity of self-reported health care utilization have showed that accuracy of self-reported health care utilization varies according to type and frequency of utilization and might be influenced by recall time frame and mode of data collection, including questionnaire design. A number of studies quantified the extent of self-report inaccuracy in terms of variable error and bias; yet only few studies investigated how to improve accuracy of self-report and to minimize bias. Currently, conclusions about the impact of modifiable attributes of data collection, such as mode of administration and recall timeframe, on quality of resulting data are drawn from comparison of different samples or – at best – from within subject comparisons. Studies using experimental methods, for example, randomized allocation of different questionnaire modes to participants are lacking.

Recall time frame represents an important attribute of data collection, since the choice of a particular recall period would often determine intervals of data collection, which, in turn, has important implications in terms of costs of data collection. Moreover, interval of data collection can also influence response rates. An optimal recall period probably depends on the type of utilization, and perhaps more important, on the utilization frequency, since there is strong evidence that underreporting is associated with increased utilization volume (see e.g. (Bellon *et al.*, 2000; Kashner *et al.*, 1999; Ritter *et al.*, 2001; Roberts *et al.*, 1996; Cleary and Jette, 1984; Schmitz *et al.*, 2002; Wallihan *et al.*, 1999; Weissman *et al.*, 1996). Therefore, researchers interested in asking about self-reported utilization for frequently used medical care should probably shorten the recall period. The common practice is to avoid recall time frames greater than 12 months for salient events such as hospitalizations; 6 and 3 months are frequently chosen as recall limit to capture utilization of outpatient services; recall period of 7 to14 days is typical for collection of medication use data. However, no experimental studies exploring optimal recall period for various categories of health-related resource utilization were identified. Few studies explicitly exploring influence of recall period used within subject comparison as a method of investigation (Mauldin *et al.*, 2008; Bellon *et al.*, 2000; Petrou *et al.*, 2002). Yet, the two–time frame approach may produce greater accuracy of self-report and the generalisability of results of these studies remains questionable.

The current version of the questionnaire we developed is currently employed in several within-trial economic evaluations of interventions to treat depression in patients with diabetes (Chernyak *et al.*, 2009; Chernyak *et al.*, 2010).These within-trial economic evaluations will provide evidence on the specific impact of depression treatment on health-related resource utilization and cost based on patient self-report. Our current research on the validity of self-reported healthcare use will complement these findings, and allow estimating their accuracy.

A fruitful area of methodological research for health surveys and economic evaluations may be in developing better and more efficient mechanisms for respondents to track their health care use between interviews and ways to encourage more respondents to use these tools.

Given the widespread use of self-report method in large national health surveys and in RCTs, the paucity of experimental research with regard to important attributes of data collection as well as the absence of best practice recommendations to guide data collection and to improve accuracy of self-reported health care utilization is surprising.

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Attachment I

Teil I : Gesundheit und medizinische Versorgung

Bitte beantworten Sie die Fragen möglichst vollständig. Falls Sie die erforderlichen Angaben nicht genau machen können, schätzen Sie bitte.

Nur für die Interviews:

Wenn Sie Probleme im Verständnis oder bei der Beantwortung haben, bitte markieren Sie die Frage (z.B. umkreisen Sie die Nummer der Frage). Wir möchten Sie dann später darauf ansprechen.

Fragen zu Diabetes und anderen Erkrankungen

1. Welchen Diabetes-Typ haben Sie?

☐ Typ-1

☐ Typ-2

☐ Anderer ________________________________

☐ weiß ich nicht

2. Wann wurde der Diabetes bei Ihnen zum ersten Mal diagnostiziert?

☐ vor _______ Jahren

(wenn Diagnose weniger als 1 Jahr zurückliegt, geben Sie bitte in etwa die Zahl der Monate an):

☐ weiß ich nicht

Wie genau ist Ihre Angabe?

ziemlich genau　　eher ungenau　　grob geschätzt

3. Bitte markieren Sie, welche sonstigen Erkrankungen Ihre Ärztin/Ihr Arzt bei Ihnen festgestellt hat:

Erkrankungen der Niere (z.B. Eiweißausscheidung im Urin)

☐ Nein　　☐ Ja　　☐ weiß ich nicht

Dialysepflichtigkeit (Blutwäsche)

☐ Nein　　☐ Ja　　☐ weiß ich nicht

Erkrankungen der Augen (Schäden am Augenhintergrund, Lasern am Auge)

☐ Nein　　☐ Ja　　☐ weiß ich nicht

Erkrankungen der Nerven an den Beinen/ Füßen (z.B. Brennen, Kribbeln oder Taubheitsgefühl)

☐ Nein　　☐ Ja　　☐ weiß ich nicht

„Diabetisches Fußsyndrom“ (offene entzündete Wunden an den Füßen, die nicht schnell heilen)

|__| Nein |__| Ja |__| weiß ich nicht

Amputation an Füßen/Beinen

|__| Nein |__| Ja |__| weiß ich nicht

Periphere arterielle Verschlusskrankheit (**Schmerzen in den Beinen oder Waden** beim Gehen, **weshalb Sie stehen bleiben** müssen, damit der Schmerz nachlässt)

|__| Nein |__| Ja |__| weiß ich nicht

Herzinfarkt

|__| Nein |__| Ja |__| weiß ich nicht

Bypass- oder Stent-Operation am Herzen

|__| Nein |__| Ja |__| weiß ich nicht

Schlaganfall oder Durchblutungsstörungen im Gehirn

|__| Nein |__| Ja |__| weiß ich nicht

Krebserkrankung

|__| Nein |__| Ja |__| weiß ich nicht

Sonstige Erkrankungen:

|__| Nein |__| Ja |__| weiß ich nicht

Falls Ja, welche

____

____

____

____

Sind irgendwelche Begriffe unklar geblieben?

Sind Erkrankungen, die Sie selbst haben, hier nicht aufgeführt?

4. Haben Sie einen Schwerbehindertenausweis?

|__| Nein |__| Ja

Wenn ja, welchen Grad der Schwerbehinderung haben Sie?

____

Fragen zur Behandlung allgemein

5. Haben Sie in den letzten 6 Monaten Ihre Hausärztin/Ihren Hausarzt aufgesucht oder haben Sie einen Hausbesuch bestellen müssen?

|__| Nein |__| Ja,

Wenn „ja" - Wie oft war dies in etwa?

_________ mal

An was haben Sie den Zeitraum festgemacht, wie haben sie herausgefunden, wie oft das war?

Wie genau können Sie sich an die Häufigkeit der Kontakte erinnern?

ziemlich genau eher ungenau grob geschätzt

6. Haben Sie in den letzten 6 Monaten Krankenhaus-Ambulanzen, den ärztlichen Notdienst, Notarzt o. ä. wegen eines Notfalls in Anspruch genommen?

|__| Nein

|__| Ja, nämlich ___ mal

wegen____

____

____

(bitte beschreiben Sie kurz, was gemacht wurde)

7. Haben Sie <u>in den letzten 6 Monaten</u> niedergelassene Ärzte der folgenden Fachrichtungen in Anspruch genommen?

Internist	☐ Nein	☐ Ja	Ungefähr _______mal
Diabetologe	☐ Nein	☐ Ja	Ungefähr _______mal
Kardiologe (Herzarzt)	☐ Nein	☐ Ja	Ungefähr _______mal
Nephrologe (Nierenarzt)	☐ Nein	☐ Ja	Ungefähr _______mal
Urologe	☐ Nein	☐ Ja	Ungefähr _______mal
Gynäkologe	☐ Nein	☐ Ja	Ungefähr _______mal
Orthopäde	☐ Nein	☐ Ja	Ungefähr _______mal
Gefäßchirurg	☐ Nein	☐ Ja	Ungefähr _______mal
Radiologe (Röntgenarzt)	☐ Nein	☐ Ja	Ungefähr _______mal
Neurologe	☐ Nein	☐ Ja	Ungefähr _______mal
Hals-Nasen-Ohrenarzt	☐ Nein	☐ Ja	Ungefähr _______mal
Augenarzt	☐ Nein	☐ Ja	Ungefähr _______mal
Hautarzt	☐ Nein	☐ Ja	Ungefähr _______mal
Arzt für Psychosomatik	☐ Nein	☐ Ja	Ungefähr _______mal
Psychiater	☐ Nein	☐ Ja	Ungefähr _______mal
Sonstige Ärzte:	___________________________ *(Fachrichtung)*		Ungefähr _______mal
	___________________________ *(Fachrichtung)*		Ungefähr _______mal
	___________________________ *(Fachrichtung)*		Ungefähr _______mal
	___________________________ *(Fachrichtung)*		Ungefähr _______mal

Wie schwer war es für Sie, sich an die letzten 6 Monate zurückzuerinnern?

Wie genau können Sie sich an die Häufigkeit der Kontakte erinnern?

ziemlich genau eher ungenau grob geschätzt

Was würden Sie unter „niedergelassen“ verstehen?

Sind Ihnen irgendwelche Arzt-Bezeichnungen nicht bekannt oder unklar?

8. Bitte schätzen Sie wie viel Zeit alle Ihre Arztbesuche insgesamt <u>in den letzten 6 Monaten</u> gekostet haben:

etwa_____ Stunden (Beziehen Sie dabei Ihre An- und Abfahrt sowie die Wartezeit beim Arzt mit ein!)

Wie sind Sie auf den Stundenwert gekommen?

Sind Ihre Angaben

ziemlich genau eher ungenau grob geschätzt

9. Wurden bei Ihnen die folgenden medizinischen Spezialuntersuchungen <u>in den letzten 6 Monaten</u> durchgeführt?

Sonographie (Ultraschall-untersuchung)	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa): ______mal	Falls ja, was wurde untersucht: ________________
Röntgen	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa): ______mal	Falls ja, was wurde untersucht: ________________
Spiegelung von Magen oder Darm?	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa):	Falls ja, was wurde untersucht:

			______mal	____________________
Computer-tomographie	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa): ______mal	Falls ja, was wurde untersucht: ____________________
Kernspin-tomographie	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa): ______mal	Falls ja, was wurde untersucht: ____________________
EKG	|__| Nein	|__| Ja	Falls ja, wie oft (in etwa): ______mal	Falls ja, was wurde untersucht: ____________________
Sonstiges (bitte kurz beschreiben): ____________________ ____________________ ____________________			Wie oft (in etwa): ____________________ ____________________ ____________________	Was wurde untersucht? ______mal ______mal ______mal

Sind Ihnen die Begriffe in den Antwortvorschlägen alle bekannt?

Wie schwer war es für Sie, sich an die letzten 6 Monate zurückzuerinnern?

Wie genau können Sie sich an die Häufigkeit der Untersuchungen erinnern?

ziemlich genau eher ungenau grob geschätzt

10. Haben Sie <u>in den letzten 6 Monaten</u> einen Psychotherapeuten aufgesucht?

|__| Nein

|__| Ja, nämlich:

Anzahl Kontakte	**Selbstgetragene Kosten* in €*** ***Sofort nach Definition fragen**	**Zeitaufwand in Stunden**
Ungefähr _____mal	(etwa) _______€.	(etwa) _______Stunden.

*Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte. Sollten Sie den Betrag auch nicht schätzen können, tragen Sie bitte ein Fragezeichen ein.

Würden Sie einen Unterschied machen zwischen Psychotherapeut, Psychologe und Psychiater?

*Was verstehen Sie unter „selbstgetragenen Kosten“?

Wie sind Sie auf den Wert gekommen?

Wie sind Sie auf den Zeitaufwand gekommen?

Sind Ihre Angaben

ziemlich genau eher ungenau grob geschätzt

11. Haben Sie <u>in den letzten 6 Monaten</u> einen Krankengymnasten, Heilpraktiker oder andere Therapeuten aufgesucht?

|__| Nein

|__| Ja, nämlich:

Therapeut **(Fachrichtung)**	**Anzahl der Kontakte**	**Leistungen (bitte kurz beschreiben)**	**Selbstgetragene Kosten in €*** ***Sofort nach Definition fragen**	**Zeitaufwand in Stunden**
Krankengymnast	Ungefähr ______mal		(etwa) ________€	(etwa) _____ Std.
Heilpraktiker	Ungefähr ______mal		(etwa) ________€	(etwa) _____ Std.
Sonstige Therapeuten(bitte benennen): _______________ _______________ _______________	____mal ____mal ____mal		_______€ _______€ ________€	_____ Std. _____ Std. _____ Std.

*Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte. Sollten Sie den Betrag auch nicht schätzen können, tragen Sie bitte ein Fragezeichen ein.

Wie schwer war es für Sie, sich an die letzten 6 Monate zurückzuerinnern?

Wie genau können Sie sich an die Häufigkeit der Kontakte erinnern?

ziemlich genau eher ungenau grob geschätzt

Wie sind Sie auf den Wert gekommen? Ist Ihre Angabe …

ziemlich genau eher ungenau grob geschätzt

Wie sind Sie auf den Zeitaufwand gekommen?

ziemlich genau eher ungenau grob geschätzt

Fallen Ihnen noch andere Therapeuten ein, die Sie hier zuordnen würden?

12. Wurden Sie in den letzten 6 Monaten in einem Krankenhaus AMBULANT behandelt (ausgenommen Notfallbehandlungen und Übernachtungen im Krankenhaus)?

☐ Nein

☐ Ja , nämlich _______mal

wegen____

(bitte beschreiben Sie kurz, was dort gemacht wurde)

13. Waren Sie in den letzten 6 Monaten in einem Krankenhaus zur STATIONÄREN Behandlung?

☐ Nein

☐ Ja , nämlich:

Name und Adresse der Einrichtung	**Abteilung**	**Aufnahmegrund bzw. Grund des Aufenthalts**	**Ist eine Operation durchgeführt worden?**	**Verweildauer (Anzahl Tage oder Wochen)**
			☐ Ja ☐ Nein	___Tage oder ___Wochen
			☐ Ja ☐ Nein	___Tage oder ___Wochen
			☐ Ja ☐ Nein	___ Tage oder ___ Wochen
			☐ Ja ☐ Nein	___ Tage oder ___ Wochen

Wie gut können Sie sich an die Verweildauer erinnern?

(Nur bei etwaigem KH-Aufenthalt)

ziemlich genau eher ungenau grob geschätzt

14. Wurde bei Ihnen in den letzten 6 Monaten eine ambulante Rehabilitationsmaßnahme durchgeführt oder waren Sie in einer Reha-Klinik?

☐ Nein

☐ Ja, und zwar:

Name und Adresse der Einrichtung	Grund der Reha	Ambulant oder stationär	Verweildauer (Anzahl Tage oder Wochen)
		☐ ambulant ☐ stationär	____ Tage oder ____ Wochen
		☐ ambulant ☐ stationär	____ Tage oder ____ Wochen

Fragen zur Behandlung des Diabetes

15. Wie wird Ihr Diabetes gegenwärtig (d. h. in den letzten 2 - 4 Wochen) behandelt? (Mehrere Angaben sind möglich)

Mit Diät und Bewegung	☐ Nein	☐ Ja
Mit blutzuckersenkenden Tabletten	☐ Nein	☐ Ja
Mit Spritzen von Byetta oder Victoza	☐ Nein	☐ Ja
Mit Insulin	☐ Nein	☐ Ja

Sind Ihnen hier alle Begriffe bekannt?

16. **Haben sich bei Ihrer Diabetes-Therapie <u>in den letzten 6 Monaten</u> Änderungen ergeben?** Bitte schauen Sie mit mir gemeinsam in die Tabelle (mögliche Vorschläge sind dort angegeben)

|__| Nein

|__| Ja, und zwar:

Blutzuckersenkende Tabletten z.B.: Metformin, Amaryl, Glimepirid, Januvia, Eucreas, Galvus, Euglucon, Onglyza, Avandia, Actos	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____
Byetta oder Victoza	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____
Insulin	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____ Ungefähr seit ___ ____ ____

Ist die Tabelle für Sie verständlich gestaltet? Oder gibt es hier Ihrer Meinung nach Probleme?

Wie schwierig war es für Sie, sich an den Zeitpunkt der Änderungen zu erinnern? Sind Ihre Angaben

ziemlich genau eher ungenau grob geschätzt

Frage 17 nur, wenn Sie mit blutzuckersenkenden Tabletten behandelt werden

17. Falls Sie gegenwärtig mit blutzuckersenkenden Tabletten behandelt werden, geben Sie bitte an, welche Tabletten Sie einnehmen und in welcher Menge:

Name der Tabletten (Nur die für den Diabetes angeben!)*	**Zahl der Tabletten pro Tag (= Tagesdosis) in den letzten 4 Wochen**
* Bitte geben Sie den genauen Namen an, z.B. „Glibenclamid 3,5“)	
1.	
2.	
3.	
4.	
5.	
6.	

Frage 18 nur, wenn Sie mit Byetta oder Victoza behandelt werden

18. Falls Sie mit Byetta oder Victoza gegenwärtig behandelt werden, geben Sie bitte an, welches der Medikamente Sie benutzen und in welcher Menge:

Name des Medikaments	**Übliche oder durchschnittliche Tagesdosis in den letzten 4 Wochen**
|__| Byetta 5µg	___________ mal am Tag
|__| Byetta10µg	___________ mal am Tag
|__| Victoza (3ml-Pen)	___________ ml ___________ mal am Tag

Fragen 19 bis 21 nur, wenn Sie mit Insulin behandelt werden

19. Falls Sie gegenwärtig mit Insulin behandelt werden, geben Sie bitte an wie Sie in der Regel Insulin zuführen und welche Insuline Sie erhalten:

Art der Insulin-Zuführung	**Name des Insulinpräparates***	**Übliche oder durchschnittliche Insulinmenge pro Tag in der letzten Woche (Einheiten pro Tag)**	**Wie häufig spritzen Sie pro Tag Insulin?**
|__| Pen zum Füllen mit Patronen			
|__| Fertig-Pen (wenn leer, wird er weggeworfen =Einweg)			
|__| Herkömmliche Injektionsspritze			
|__| Insulinpumpe			☒

*Bitte geben Sie alle Insulinpräparate an, die Sie verwenden und benennen Sie bitte den genauen Insulinnamen, der auf der Verpackung steht. Dabei sind auch die Zahlen nach dem Namen wichtig (z.B. 100 IU). Bitte geben Sie für jedes Insulinpräparat die entsprechende Menge, also Einheiten, die Sie spritzen pro Tag an.

Wenn Patient Pumpe hat, Frage 20 weglassen!

20. Bitte geben Sie an, ob Sie Insulin in vom Arzt fest vorgegebener täglicher Menge spritzen oder ob Sie mit dem Arzt eine „flexible Therapie“ vereinbart haben, d.h. dass Sie die Einheiten pro Mahlzeit oder Tageszeit selbständig bestimmen:

|___| Insulin-Menge fest vorgegeben

|___| Insulinmenge selbst nach Bedarf bestimmt

Bitte können Sie in eigenen Worten wiedergeben, was wir mit dieser Frage meinen?

21. Haben Sie die Art der Insulin-Zuführung (Spritze, Pen, Pumpe) in den letzten 6 Monaten gewechselt?

|__| Nein

|__| Ja, und zwar von _____________ auf_________ ungefähr seit___ ____ ____

Woran haben Sie den Zeitpunkt der Änderung festgemacht?

22. Wie häufig messen Sie gegenwärtig Ihren Blutzucker?

In der letzten Woche etwa ________mal pro Tag

bzw. etwa ________mal pro Woche

Weitere Medikamente

23. Bitte nennen Sie *weitere* Medikamente, die Sie *zusätzlich zu Ihrer Diabetes-Therapie* REGELMÄSSIG einnehmen? (Die Medikamente, die Sie nur bei Bedarf nehmen, werden später abgefragt!)

|___| **Ich nehme zurzeit keine weiteren Medikamente ein**

Name des Arzneimittels	**Darreichungsform (Tabletten mit Dosisangabe, Tropfen etc.) und Tagesdosis** **z.B. „Diclofenac 50, 2 mal pro Tag“**	**Seit wann nehmen Sie das Medikament**
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____
		Ungefähr seit ___ ____ ____

Was verstehen Sie unter „regelmäßig“?

Wie schwer fällt es Ihnen sich an alle Medikamente und deren Dosierung zu erinnern?

Wie gut konnten Sie sich an den Zeitpunkt erinnern, seit wann Sie das Medikament einnehmen?

ziemlich genau eher ungenau grob geschätzt

24. Gibt es *weitere Medikamente*, die Sie in den letzten 6 Monaten NACH BEDARF eingenommen haben?

|__| Nein

|__| Ja, und zwar:

Name des Arzneimittels	**Darreichungsform (Tabletten, Tropfen etc.) und Dosierung**	**Wie oft ?** **(Anzahl der Tage)**
		Etwa ______Mal
		Etwa ______Mal
		Etwa ______Mal
		Etwa ______Mal
		Etwa ______Mal
		Etwa ______Mal

Was verstehen Sie unter der Definition „nach Bedarf“?

Wie schwer war es für Sie sich an die letzten 6 Monate zurück zu erinnern?

25. Wie viel haben Sie für den Kauf Ihrer Medikamente in den letzten 6 Monaten selbst aufgewendet (inklusive Ausgaben für Rezeptgebühren)? Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte:

(etwa) ________€.

Wie sind Sie auf den Betrag gekommen?

Wie genau würden Sie sagen ist die Betragsangabe?

ziemlich genau   eher ungenau   grob geschätzt

26. Nehmen Sie an einem *Disease-Management-Programm (DMP)* teil? Gemeint sind spezielle Programme, die von den Krankenkassen für chronisch Kranke Patienten über den Hausarzt/ behandelnden Arzt angeboten werden und in die Sie sich eintragen mussten.

|__| Nein

|__| Ja, nämlich:

|__| DMP für Diabetes

|__| anderes DMP – dann welches?:______________________________________

|__| Weiß ich nicht

Ist Ihnen der Begriff DMP bekannt? Bzw. was damit gemeint ist?

27. Haben Sie in den letzten 6 Monaten an Kursen oder Schulungen in Bezug auf Ihre Gesundheit teilgenommen (z.B. Kurse über Ernährung o.ä.)?

|__| Nein

|__| Ja, und zwar:

Kurze Beschreibung	**Aufgewendete Zeit in Stunden**	**Selbstgetragene Kosten in €***
	(etwa) _______St.	(etwa) _______€
	(etwa) _______St.	(etwa) _______€

*Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte. Sollten Sie den Betrag auch nicht schätzen können, tragen Sie bitte ein Fragezeichen ein.

Was würden Sie sonst noch zu solchen gesundheitsfördernden Kursen zählen?

28. Welche Art der Krankenversicherung haben Sie?

|__| gesetzlich
|__| privat
|__| gesetzlich mit privater Zusatzversicherung

Teil II: Gesundheit, Alltag und Beruf

29. Wie waren Sie in den letzten 6 Monaten beruflich beschäftigt?

|__| voll erwerbstätig (mit einer wöchentlichen Arbeitszeit von 35 Stunden und mehr)

|__| teilzeitbeschäftigt

|__| arbeitslos

|__| erwerbsunfähig

|__| Rentner(in), Pensionär(in), im Vorruhestand

|__| Sonstige Tätigkeit ______________________________

30. Waren Sie in den letzten 6 Monaten arbeitsunfähig/ krank geschrieben?

|__| Nein

|__| Ja, für insgesamt (ungefähr)_______Tage

Falls ja,

Wie genau konnten Sie sich daran erinnern, wie viele Tage sie arbeitsunfähig waren?

ziemlich genau eher ungenau grob geschätzt

31. Gab es in den letzten 4 Wochen Tage, an denen Sie wegen Ihres Gesundheitszustandes mehr als die Hälfte des Tages im Bett verbringen mussten und Ihren üblichen Aktivitäten nicht nachgehen konnten?

|__| Nein

|__| Ja, nämlich _____Tage

32. Haben Sie wegen Ihres Gesundheitszustandes in den letzten 4 Wochen Hilfe für Arbeiten in Anspruch nehmen müssen, die Sie üblicherweise selber erledigen (z.B. um den Haushalt oder Einkäufe zu erledigen)?

|__| Nein

|__| Ja, nämlich:

Art der Hilfen	**Durchschnittlicher Zeitaufwand pro Woche in Stunden**	**Durchschnittliche Kosten pro Woche falls nicht von der Sozialversicherung erstattet***
Hilfe von Familienangehörigen, Freunden oder Bekannten	(etwa) _______St	(etwa) _______€
Haushaltshilfen	(etwa) _______St	(etwa) _______€
Ambulante Pflegedienste (z.B. Caritas)	(etwa) _______St	(etwa) _______€

*Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte. Sollten Sie die Kosten nicht wissen, tragen Sie bitte ein Fragezeichen ein.

Wie schwierig ist es, den Zeitaufwand zu schätzen? Sind Ihre Angaben

ziemlich genau   eher ungenau   grob geschätzt

Wie sind Sie auf die durchschnittlichen Kosten gekommen? Sind Ihre Angaben

ziemlich genau   eher ungenau   grob geschätzt

33. Haben Sie in den letzten 6 Monaten eine Erwerbsunfähigkeitsrente beantragt?

|__| Nein

|__| Ja

34. Ist Ihr Rentenantrag schon bewilligt worden?

|__| Nein

|__| Ja, der Bescheid gilt ab ___ ____ _____

Allgemeines zu dem Fragebogen

1. Wie empfanden Sie die Situation? War Ihnen irgendetwas unangenehm? Ist der Fragebogen evtl. zu umfangreich, ermüdend?
2. Wäre es für Sie einfacher sich an zeitliche Begebenheiten zu erinnern, wenn wir nur einen Zeitraum von 3 Monaten abfragen würden?
3. Welche Befragungsform würde Sie bevorzugen? Persönliches Interview oder schriftliche Beantwortung der Fragen?
4. Haben Sie Verbesserungsvorschläge (Anpassung von Begriffen, Zusätzliche Ausgaben)

Attachment II

A standardized behavior coding form (example)

<table>
<tr><td>**Frage 5**</td><td>Haben Sie in den letzten 6 Monaten Ihre Hausärztin/Ihren Hausarzt aufgesucht oder haben Sie einen Hausbesuch bestellen müssen?</td></tr>
<tr><td colspan="2">**Verhalten des Befragten**</td></tr>
<tr><td colspan="2">**Behavior Coding**</td></tr>
<tr><td colspan="2">|__| Teilnehmer will Klärung</td></tr>
<tr><td colspan="2">|__| Teilnehmer macht zusätzliche Bemerkungen</td></tr>
<tr><td colspan="2">|__| Frage nicht adäquat beantwortet</td></tr>
<tr><td colspan="2">|__| Weiß ich nicht</td></tr>
<tr><td colspan="2">|__| Frage nicht beantwortet</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">**Confidence rating zu Angaben zu Häufigkeit der Kontakte**
|__| ziemlich genau
|__| eher ungenau
|__| grob geschätzt</td></tr>
<tr><td colspan="2">**Sonstige Probleme:**</td></tr>
</table>

Frage 7	Haben Sie in den letzten 6 Monaten niedergelassene Ärzte der folgenden Fachrichtungen in Anspruch genommen?

Verhalten des Befragten

Behaviour Coding

|__| Teilnehmer will Klärung

|__| Teilnehmer macht zusätzliche Bemerkungen

|__| Frage nicht adäquat beantwortet

|__| Weiß ich nicht

|__| Frage nicht beantwortet

Confidence rating zu Angaben zu Häufigkeit der Kontakte beim

|__| ziemlich genau |__| eher ungenau |__| grob geschätzt	|__| ziemlich genau |__| eher ungenau |__| grob geschätzt	|_| ziemlich genau |__| eher ungenau |__| grob geschätzt	|__| ziemlich genau |__| eher ungenau |__| grob geschätzt	|x_| ziemlich genau |__| eher ungenau |__| grob geschätzt

Probing

Was würden Sie unter dem Begriff „niedergelassen“ verstehen?

Begriffe/Arzt-Bezeichnungen unklar

Sonstiges

Attachment III

Fragebogen

zu Gesundheit und medizinischer Versorgung

Herzlichen Dank, dass Sie an dieser Befragung teilnehmen!

DDZ

Deutsches Diabetes-

HEINRICH HEINE
UNIVERSITÄT
DÜSSELDORF

pronova BKK
PARTNER FÜR IHRE GESUNDHEIT

Diabetes, andere Erkrankungen und gesundheitliche Probleme

1. Welchen Diabetes-Typ haben Sie?

Typ-1 ☐

Typ-2 („Altersdiabetes“) ☐

Anderer ☐

und zwar: ____________________

weiß ich nicht ☐

2. Wann wurde der Diabetes bei Ihnen diagnostiziert?

vor _______ Jahren oder Jahresangabe: __________

vor _______ Monaten (wenn Diagnose weniger als 1 Jahr zurückliegt)

weiß ich nicht ☐

3. Auf den folgenden Seiten finden Sie eine Auflistung verschiedener Erkrankungen. Bitte geben Sie an, welche dieser Erkrankungen Sie haben bzw. <u>in den letzten 12 Monaten</u> hatten. Gemeint sind Erkrankungen, die Ihre Ärztin/ Ihr Arzt bei Ihnen festgestellt hat.

Falls Sie in der ersten Spalte „Nein“ ankreuzen, fahren Sie bitte direkt mit der nächsten Erkrankung in der darunterliegenden Zeile fort. Falls Sie „Ja“ ankreuzen, geben Sie bitte an, ob Sie sich aufgrund dieser Erkrankung in (ärztlicher) Behandlung befinden und ob diese Erkrankung Sie in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit) beeinträchtigt. Am Ende der Liste haben Sie die Möglichkeit, weitere Erkrankungen zu ergänzen, die bislang nicht aufgeführt wurden.

Probanden-ID: ______

Erkrankung	**Ist die Erkrankung von Ihrer Ärztin/ Ihrem Arzt festgestellt worden?**	**Befinden Sie sich deshalb in (ärztlicher) Behandlung?**	**Wie stark beeinträchtigt Sie diese Erkrankung in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit)?**
Hypertonie (Bluthochdruck)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Periphere arterielle Verschlusskrankheit („Schaufensterkrankheit“: Schmerzen in den Beinen oder Waden beim Gehen, weshalb Sie stehen bleiben müssen, damit der Schmerz nachlässt)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Durchblutungsstörungen am Herzen (Angina pectoris)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Herzinfarkt	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Herzinsuffizienz (Herzschwäche)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Durchblutungsstörung des Gehirns	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Schlaganfall	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
TIA	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Erkrankungen der Augen (z.B. Schäden am Augenhintergrund, Katarakt)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Erkrankungen der Nerven an den Beinen bzw. Füßen (z.B. Brennen, Kribbeln oder Taubheitsgefühl)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark

Probanden-ID: ______

Erkrankung	**Ist die Erkrankung von Ihrer Ärztin/ Ihrem Arzt festgestellt worden?**	**Befinden Sie sich deshalb in (ärztlicher) Behandlung?**	**Wie stark beeinträchtigt Sie diese Erkrankung in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit)?**
Entzündungen, Geschwüre oder Wunden an den Füßen, die schlecht heilen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Amputation an Füßen/ Beinen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Erkrankungen der Niere (z.B. Eiweißausscheidung im Urin)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Dialysepflichtigkeit (Blutwäsche)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Krebserkrankung (bösartiger Tumor)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Schilddrüsenerkrankung	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Gicht	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Chronische (andauernde) Rückenschmerzen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Entzündliche Gelenk- oder Wirbelsäulenerkrankung (z.B. Arthritis)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Sonstige Gelenk- oder Wirbelsäulenerkrankung	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Magen- oder Zwölffingerdarmgeschwür oder chronische Magenschleimhautentzündung	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Entzündliche Darmerkrankung (z.B. Colitis Ulcerosa, Morbus Crohn)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Sonstige Darmerkrankung	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark

Probanden-ID: ____________

Erkrankung	Ist die Erkrankung von Ihrer Ärztin/ Ihrem Arzt festgestellt worden?	Befinden Sie sich deshalb in (ärztlicher) Behandlung?	Wie stark beeinträchtigt Sie diese Erkrankung in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit)?
Gallensteine	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Häufige Harnwegsinfektionen (Blasenentzündung)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Chronische Leberentzündung (Hepatitis)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Allergie(n), Heuschnupfen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Asthma bronchiale	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Chronische Bronchitis oder chronisch obstruktive Lungenerkrankung (COPD)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Blutarmut (Anämie)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Chronische Hautkrankheiten (z.B. Neurodermitis, Schuppenflechte/ Psoriasis)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Migräne	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Epilepsie	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Parkinson-Krankheit	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Depression	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Sonstige Erkrankung, und zwar: ____________________	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Sonstige Erkrankung, und zwar: ____________________	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark

4. Möglicherweise haben Sie neben den oben genannten Erkrankungen weitere Beschwerden oder gesundheitliche Probleme. Bitte markieren Sie in der folgenden Auflistung, welche der genannten Beschwerden oder gesundheitlichen Probleme Sie haben bzw. <u>in den letzten 12 Monaten</u> hatten.

Falls Sie in der ersten Spalte „Nein“ ankreuzen, fahren Sie bitte direkt mit dem nächsten gesundheitlichen Problem in der darunterliegenden Zeile fort. Falls Sie „Ja“ ankreuzen, geben Sie bitte an, ob Sie sich aufgrund dieses Problems in (ärztlicher) Behandlung befinden und ob dieses Problem Sie in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit) beeinträchtigt. Sie haben zusätzlich die Möglichkeit, weitere Beschwerden zu ergänzen, die bislang nicht aufgeführt wurden.

Gesundheitliches Problem	**Haben Sie dieses gesundheitliche Problem?**	**Befinden Sie sich deshalb in (ärztlicher) Behandlung?**	**Wie stark beeinträchtigt Sie dieses gesundheitliche Problem in der Ausübung Ihrer täglichen Aktivitäten (Arbeit bzw. Freizeit)?**
Magen-Darm Probleme (z.B. häufige Bauchschmerzen, Verdauungsstörung)	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Gelenkschmerzen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Kopfschmerzen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Herz- oder Brustschmerzen	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Chronischer (lang andauernder) Husten	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Schwierigkeiten beim Atmen, Atemnot	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Schlafstörung	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Schwindelgefühl	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark
Sonstige Schmerzen oder Beschwerden, und zwar: ____________________	☐ Ja ☐ Nein	☐ Ja ☐ Nein	☐ Gar nicht ☐ Ein wenig ☐ Mittelmäßig ☐ Stark ☐ Sehr stark

Probanden-ID: ________________

5. **Sind Sie <u>in den letzten 12 Monaten</u> operiert worden? Gemeint ist z.B. die Entfernung der Gallenblase, der Einsatz eines künstlichen Hüftgelenks, eine Operation am Herzen, oder eine gynäkologische Operation.**

☐ Nein ☐ Ja

Falls „ja“ beschreiben Sie bitte kurz, welche Operationen durchgeführt wurden:

____

____

____

6. **Haben Sie <u>in den letzten 6 Monaten</u> eine Verletzung erlitten, die durch einen Unfall zuhause oder im Umfeld Ihres Hauses, durch sportliche Aktivität, durch einen Arbeitsunfall oder im Straßenverkehr verursacht wurde?**

☐ Nein ☐ Ja

falls „Ja“

→ Mussten Sie deshalb ärztlich behandelt werden? ☐ Ja ☐ Nein

→ Hatten Sie einen Knochenbruch? ☐ Ja ☐ Nein

7. **Besteht bei Ihnen eine Behinderung, die vom Versorgungsamt anerkannt ist?**

☐ Nein ☐ Ja

falls „Ja“

→ Welchen Grad der Schwerbehinderung haben Sie? ____________%

Allgemeine medizinische Versorgung

8. Waren Sie in den letzten 6 Monaten bei den folgenden Ärzten? Gemeint sind AMBULANTE Kontakte zu den Ärzten oder deren Praxispersonal (ausgenommen Behandlungen im Krankenhaus). Bitte berücksichtigen Sie hier auch die Praxisbesuche zur Abholung von Rezepten oder Überweisungen und zur Krankschreibung!

Fachrichtung des Arztes	**In Anspruch genommen**	**Anzahl der Kontakte in den letzten 6 Monaten**
Hausarzt	☐ Nein ☐ Ja	_______ mal
Internist (falls nicht Ihr Hausarzt)*	☐ Nein ☐ Ja	_______ mal
Diabetologe (falls nicht Ihr Hausarzt)*	☐ Nein ☐ Ja	_______ mal
Kardiologe (Arzt für Herzkrankheiten)	☐ Nein ☐ Ja	_______ mal
Nephrologe (Arzt für Nierenkrankheiten)	☐ Nein ☐ Ja	_______ mal
Urologe	☐ Nein ☐ Ja	_______ mal
Gynäkologe	☐ Nein ☐ Ja	_______ mal
Orthopäde	☐ Nein ☐ Ja	_______ mal
Gefäßchirurg	☐ Nein ☐ Ja	_______ mal
Radiologe (Röntgenarzt)	☐ Nein ☐ Ja	_______ mal
Hals-Nasen-Ohrenarzt	☐ Nein ☐ Ja	_______ mal
Augenarzt	☐ Nein ☐ Ja	_______ mal
Dermatologe (Hautarzt)	☐ Nein ☐ Ja	_______ mal
Neurologe	☐ Nein ☐ Ja	_______ mal
Arzt für Psychosomatik (keine Psychotherapie)**	☐ Nein ☐ Ja	_______ mal
Psychiater (keine Psychotherapie)**	☐ Nein ☐ Ja	_______ mal
Sonstiger Arzt *(bitte benennen)*:	☐ Nein ☐ Ja	_______ mal
Sonstiger Arzt *(bitte benennen)*:	☐ Nein ☐ Ja	_______ mal

*Falls Ihr Diabetologe bzw. Ihr Internist zugleich ihr Hausarzt ist, machen Sie bitte entsprechende Angaben nur einmal.

**Bitte nur Kontakte angeben, die einen anderen Anlass als eine Psychotherapie hatten. Psychotherapie wird unten erfragt.

9. Haben Sie <u>in den letzten 6 Monaten</u> einen Hausbesuch bestellen müssen?

|__| Ja, nämlich _______ mal |__| Nein

10. Wurden Sie <u>in den letzten 6 Monaten</u> in einem Krankenhaus AMBULANT behandelt (ausgenommen Notfallbehandlungen und Übernachtungen im Krankenhaus)?

|__| Ja, nämlich _______ mal |__| Nein

Falls „ja“ beschreiben Sie bitte kurz, was dort gemacht wurde:

____

____

____

11. Haben Sie <u>in den letzten 6 Monaten</u> eine Krankenhaus-Ambulanz oder ärztlichen Notdienst/ Notarzt o.ä. <u>wegen eines Notfalls</u> aufgesucht (ausgenommen Übernachtungen im Krankenhaus)?

|__| Ja, nämlich _______ mal |__| Nein

Falls „ja“ beschreiben Sie bitte kurz, was gemacht wurde:

____

____

____

12. Bitte schätzen Sie, wie viel Zeit Sie für Ihre ambulanten Arztbesuche in den letzten 6 Monaten aufgewendet haben. Machen Sie bitte entsprechende Angaben in Minuten oder Stunden.

	An- und Abfahrtzeit	**Wartezeit**	**Behandlungszeit**
Hausarzt	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Internist (wenn nicht Ihr Hausarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Diabetologe (wenn nicht Ihr Hausarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Kardiologe (Herzarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Nephrologe (Nierenarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Urologe	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Gynäkologe	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Orthopäde	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Gefäßchirurg	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Radiologe (Röntgenarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Hals-Nasen-Ohrenarzt	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Augenarzt	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Dermatologe (Hautarzt)	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Neurologe	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Arzt für Psychosomatik	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Psychiater	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Sonstiger Arzt:	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Sonstiger Arzt:	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Ambulante Behandlung im Krankenhaus	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h
Notfallbehandlungen	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h	|____| Min. bzw. |____| h

13. Wurden bei Ihnen die folgenden medizinischen Spezialuntersuchungen <u>in den letzten 6 Monaten</u> AMBULANT durchgeführt? Bitte alles Zutreffende ankreuzen!

|__| Nein
|__| Ja, nämlich:

Untersuchung	**Ja**	**Wie oft:**	**Was wurde untersucht:**
Sonographie (Ultraschalluntersuchung)	|__|	______ mal	
Röntgen	|__|	______ mal	
Spiegelung von Magen oder Darm	|__|	______ mal	
Computertomographie (CT)	|__|	______ mal	
Kernspintomographie (MRT)	|__|	______ mal	
EKG	|__|	______ mal	
Sonstiges (*bitte kurz beschreiben*):	|__|	______ mal	
Sonstiges (*bitte kurz beschreiben*):	|__|	______ mal	
Sonstiges (*bitte kurz beschreiben*):	|__|	______ mal	

14. Waren Sie <u>in den letzten 6 Monaten</u> in einem Krankenhaus zur STATIONÄREN Behandlung?

|__| Nein

|__| Ja, nämlich:

Name und Ort der Einrichtung	**Abteilung**	**Aufnahmegrund bzw. Grund des Aufenthalts**	**Ist eine Operation durchgeführt worden?**	**Verweildauer**
			|__| Ja |__| Nein	___Tage oder ___Wochen
			|__| Ja |__| Nein	___Tage oder ___Wochen
			|__| Ja |__| Nein	___ Tage oder ___ Wochen
			|__| Ja |__| Nein	___ Tage oder ___ Wochen
			|__| Ja |__| Nein	___ Tage oder ___ Wochen

15. Haben Sie <u>in den letzten 6 Monaten</u> einen Psychotherapeuten aufgesucht?

|__| Nein

|__| Ja, nämlich:

Anzahl Kontakte	**Selbstgetragene Kosten in €* (Gesamtsumme)**	**Gesamter Zeitaufwand in Minuten oder Stunden****
_____ mal	_______ €	|____| Min. oder |____| h

* Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte.
** Falls Sie den Zeitaufwand nicht genau nennen können, schätzen Sie ihn bitte.

16. Haben Sie <u>in den letzten 6 Monaten</u> einen Krankengymnasten, Heilpraktiker oder andere Therapeuten aufgesucht?

|__| Nein

|__| Ja, nämlich:

Therapeut (Fachrichtung)	**Anzahl der Kontakte**	**Leistungen (bitte kurz beschreiben)**	**Selbstgetragene Kosten in €* (Gesamtsumme)**	**Gesamter Zeitaufwand in Minuten oder Stunden****
Krankengymnast	_____ mal		_______ €	|____| Min. oder |____| h
Heilpraktiker	_____ mal		_______ €	|____| Min. oder |____| h
Sonstiger Therapeut (*bitte benennen*):	_____ mal		_______ €	|____| Min. oder |____| h
Sonstiger Therapeut (*bitte benennen*):	_____ mal		_______ €	|____| Min. oder |____| h

* Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte.
** Falls Sie den Zeitaufwand nicht genau nennen können, schätzen Sie ihn bitte.

17. Haben Sie in den letzten 6 Monaten an Maßnahmen zur Gesundheitsförderung teilgenommen? Gemeint sind z.B. Kurse, Schulungen oder Beratungen, die sich mit Ernährung, Bewegung, Entspannung und Sport oder Fitness befassen.

☐ Nein

☐ Ja, nämlich:

Kurze Beschreibung	Selbstgetragene Kosten in €* (Gesamtsumme)	Gesamter Zeitaufwand in Minuten oder Stunden**
	________ €	☐ Min. oder ☐ h
	________ €	☐ Min. oder ☐ h
	________ €	☐ Min. oder ☐ h
	________ €	☐ Min. oder ☐ h

* Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte.
** Falls Sie den Zeitaufwand nicht genau nennen können, schätzen Sie ihn bitte.

18. Welche Art der Krankenversicherung haben Sie?

☐ gesetzlich

☐ privat

☐ gesetzlich mit privater Zusatzversicherung

19. Nehmen Sie an einem *Disease-Management-Programm (DMP)* teil? Gemeint sind spezielle Programme, die von den Krankenkassen für chronisch kranke Patienten über den Hausarzt/ behandelnden Arzt angeboten werden und in die Sie sich eintragen mussten.

|__| Ja, nämlich:

|__| DMP für Diabetes

|__| anderes DMP, bitte benennen: ________________________

|__| Nein

|__| Weiß ich nicht

Behandlung des Diabetes

20. Wie häufig messen Sie gegenwärtig Ihren Blutzucker?

________ mal pro Tag

________ mal pro Woche

|__| gar nicht

21. Wie wird Ihr Diabetes gegenwärtig (d.h. in den letzten 2-4 Wochen) behandelt?

Mehrere Angaben sind möglich!

|__| Mit Diät oder Bewegung

|__| Mit blutzuckersenkenden Tabletten

|__| Mit Insulin

|__| Sonstiges (z.B. mit Spritzen von Byetta oder Victoza): ________________________

Bitte beantworten Sie die Fragen 22 bis 24 nur wenn Sie mit Insulin behandelt werden.

22. Wie häufig spritzen Sie pro Tag Insulin?

In der Regel ____________ mal pro Tag

23. Spritzen Sie Insulin in vom Arzt fest vorgegebener täglicher Menge oder haben Sie mit dem Arzt eine „flexible Therapie“ vereinbart, d.h. Sie bestimmen die Einheiten pro Mahlzeit oder Tageszeit selbständig:

|__| Insulinmenge ist fest vorgegeben

|__| Insulinmenge wird selbst nach Bedarf bestimmt

24. Haben Sie die Art der Insulin-Zuführung in den letzten 6 Monaten gewechselt (z.B. Wechsel von Spritze zu Pen oder Pumpe)?

|__| Nein

|__| Ja, und zwar von _____________ auf _____________ ungefähr seit _______________

Gesundheit, Beruf und Alltag

25. Wie waren Sie in den letzten 6 Monaten beruflich beschäftigt?

|__| Voll erwerbstätig (mit einer wöchentlichen Arbeitszeit von 35 Stunden und mehr)

|__| Teilzeitbeschäftigt

|__| Arbeitslos

|__| Erwerbsunfähig

|__| Rentner(in), Pensionär(in), im Vorruhestand

|__| Sonstige Tätigkeit: _________________________________

26. Waren Sie in den letzten 6 Monaten krankgeschrieben?

|__| Nein

|__| Ja, für insgesamt ________ Tage

27. Gab es in den letzten 4 Wochen Tage, an denen Sie so krank waren, dass Sie Ihren üblichen (Arbeits-)Tätigkeiten nicht nachgehen konnten? Bitte denken Sie an alle Tage, an denen Sie wegen Krankheit nicht zur Arbeit gehen konnten oder Ihren üblichen Tätigkeiten nicht nachgehen konnten, auch wenn Sie nicht ärztlich krankgeschrieben waren. Falls Sie die Zahl nicht wissen, schätzen Sie bitte möglichst genau!

|__| Nein

|__| Ja, nämlich _____ Tage

28. Haben Sie wegen Ihres Gesundheitszustandes in den letzten 4 Wochen Hilfe für Arbeiten in Anspruch nehmen müssen, die Sie üblicherweise selber erledigen (z.B. um den Haushalt oder Einkäufe zu erledigen)?

|__| Nein

|__| Ja, nämlich:

Art der Hilfen	**Gesamter Zeitaufwand in Stunden***	**Selbstgetragene Kosten**** **(Gesamtsumme)**
Hilfe von Familienangehörigen, Freunden oder Bekannten	_______ h	_______ €
Haushaltshilfen	_______ h	_______ €
Ambulante Pflegedienste (z.B. Caritas)	_______ h	_______ €
Sonstiges, nämlich: ________________________________	_______ h	_______ €

* Falls Sie den Zeitaufwand nicht genau nennen können, schätzen Sie ihn bitte.
** Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte.

29. Haben Sie in den letzten 6 Monaten eine Erwerbsunfähigkeitsrente beantragt?

|__| Nein |__| Ja

Falls „Ja“, ist Ihr Rentenantrag schon bewilligt worden?

|__| Ja, der Bescheid gilt ab ___ ____ _____ |__| Nein

Angaben zu Ihrer Person

30. Ihr Geburtsjahr: ______________

31. Ihr Geschlecht: Männlich ☐ Weiblich ☐

32. Welchen Familienstand haben Sie?

Ledig ☐

Verheiratet ☐

Geschieden ☐

Verwitwet ☐

33. Leben Sie mit einem (Ehe-)Partner/ einer (Ehe-)Partnerin zusammen?

Ja ☐

Nein ☐

34. Welche Nationalität haben Sie?

Deutsch ☐

Andere ☐, nämlich: ____________________________________

Falls „andere“, wie lange wohnen Sie schon in Deutschland?

Seit _______ Jahr(en)

35. Welchen allgemeinbildenden Schulabschluss haben Sie? Bitte geben Sie nur Ihren höchsten Schulabschluss an.

Noch Schüler ☐

Schule beendet ohne Abschluss ☐

Volks-/ Hauptschulabschluss bzw. Polytechnische Oberschule
(mit Abschluss der 8. oder 9. Klasse) ☐

Mittlere Reife, Realschulabschluss bzw. Polytechnische Oberschule
(mit Abschluss der 10. Klasse) ☐

Fachhochschulreife (Abschluss einer Fachoberschule etc.) ☐

Abitur bzw. Erweiterte Oberschule mit Abschluss der 12. Klasse
(Hochschulreife) ☐

Anderer Schulabschluss und zwar: ___________________________ ☐

36. Welchen beruflichen Ausbildungsabschluss haben Sie?

Mehrere Angaben sind möglich!

Betriebliche Anlernzeit, aber keine Lehre ☐

Lehre/ Berufsfachschulabschluss ☐

Meister-, Techniker- od. gleichwertiger Fachschulabschluss ☐

Fachhochschulabschluss ☐

Hochschulabschluss ☐

Anderen beruflichen Ausbildungsabschluss, und zwar:

______________________________ ☐

Noch in beruflicher Ausbildung (Auszubildende(r), Lehrling, Berufsfachschule) ☐

Student(in) ☐

Keinen beruflichen Ausbildungsabschluss ☐

37. Welchen Beruf üben Sie aus bzw. haben Sie früher ausgeübt?

____

38. Wie viele Personen leben ständig in Ihrem Haushalt?

☐ Ich lebe alleine.

☐ Ich lebe nicht alleine. Außer mir leben im Haushalt _____ weitere Personen.

39. Wie hoch ist das monatliche Nettoeinkommen Ihres Haushaltes zur Zeit insgesamt? Gemeint ist dabei die Summe, die sich aus Lohn, Gehalt, Einkommen aus selbständiger Tätigkeit, Rente oder Pension ergibt. Rechnen Sie bitte auch die Einkünfte aus öffentlichen Beihilfen, Einkommen aus Vermietung und Verpachtung, Wohngeld, Kindergeld und sonstige Einkünfte hinzu.

Ordnen Sie sich bitte in eine der folgenden Kategorien ein:

unter 1.000 € ☐
1.000 € bis unter 1.500 € ☐
1.500 € bis unter 2.000 € ☐
2.000 € bis unter 2.500 € ☐
2.500 € bis unter 3.000 € ☐
3.000 € bis unter 3.500 € ☐
3.500 € bis unter 4.000 € ☐
4.000 € bis unter 4.500 € ☐
4.500 € bis unter 5.000 € ☐
5.000 € bis unter 6.000 € ☐
6.000 € bis unter 8.000 € ☐
über 8.000 € ☐

Gesundheitszustand

40. Bitte geben Sie an, welche Aussagen Ihren heutigen Gesundheitszustand am besten beschreiben, indem Sie ein Kreuz in ein Kästchen jeder Gruppe machen.

1. Beweglichkeit/ Mobilität

|__| Ich habe keine Probleme herumzugehen

|__| Ich habe einige Probleme herumzugehen

|__| Ich bin ans Bett gebunden

2. Für sich selbst sorgen

|__| Ich habe keine Probleme, für mich selbst zu sorgen

|__| Ich habe einige Probleme, mich selbst zu waschen oder mich anzuziehen

|__| Ich bin nicht in der Lage, mich selbst zu waschen oder anzuziehen

3. Alltägliche Tätigkeiten

(z.B. Arbeit, Studium, Hausarbeit, Familien- oder Freizeitaktivitäten)

|__| Ich habe keine Probleme, meinen alltäglichen Tätigkeiten nachzugehen

|__| Ich habe einige Probleme, meinen alltäglichen Tätigkeiten nachzugehen

|__| Ich bin nicht in der Lage, meinen alltäglichen Tätigkeiten nachzugehen

4. Schmerzen/ Körperliche Beschwerden

|__| Ich habe keine Schmerzen oder Beschwerden

|__| Ich habe einige Schmerzen oder Beschwerden

|__| Ich habe extreme Schmerzen oder Beschwerden

5. Angst/ Niedergeschlagenheit

|__| Ich bin nicht ängstlich oder deprimiert

|__| Ich bin mäßig ängstlich oder deprimiert

|__| Ich bin extrem ängstlich oder deprimiert

41. **Wie oft fühlten Sie sich <u>im Verlauf der letzten 2 Wochen</u> durch die folgenden Beschwerden beeinträchtigt?**

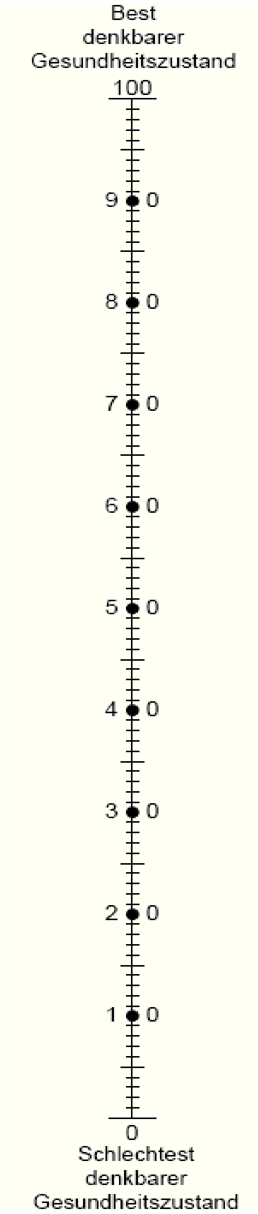
	Überhaupt nicht	**An einzelnen Tagen**	**An mehr als der Hälfte der Tage**	**Beinahe jeden Tag**
a) Wenig Interesse oder Freude an Ihren Tätigkeiten	☐	☐	☐	☐
b) Niedergeschlagenheit, Schwermut oder Hoffnungslosigkeit	☐	☐	☐	☐
c) Schwierigkeiten, ein- oder durchzuschlafen, oder vermehrter Schlaf	☐	☐	☐	☐
d) Müdigkeit oder Gefühl, keine Energie zu haben	☐	☐	☐	☐
e) Verminderter Appetit oder übermäßiges Bedürfnis zu essen	☐	☐	☐	☐
f) Schlechte Meinung von sich selbst; Gefühl ein Versager zu sein oder die Familie enttäuscht zu haben	☐	☐	☐	☐
g) Schwierigkeiten, sich auf etwas zu konzentrieren, z.B. beim Zeitungslesen oder Fernsehen	☐	☐	☐	☐
h) Waren Ihre Bewegungen oder Ihre Sprache so verlangsamt, dass es auch anderen auffallen würde? Oder waren Sie im Gegenteil „zappelig“ oder ruhelos und hatten dadurch einen stärkeren Bewegungsdrang als sonst?	☐	☐	☐	☐
i) Gedanken, dass Sie lieber tot wären oder sich Leid zufügen möchten?	☐	☐	☐	☐

42. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben?

|__| Sehr gut |__| Gut |__| Mittelmäßig |__| Schlecht |__| Sehr schlecht

43. Um Sie bei der Einschätzung, wie gut oder wie schlecht Ihr Gesundheitszustand ist, zu unterstützen, haben wir eine Skala gezeichnet, ähnlich einem Thermometer. Der best denkbare Gesundheitszustand ist mit einer "100" gekennzeichnet, der schlechteste mit "0". Wir möchten Sie nun bitten, auf dieser Skala zu kennzeichnen, wie gut oder schlecht Ihrer Ansicht nach Ihr persönlicher Gesundheitszustand heute ist. Bitte verbinden Sie dazu den untenstehenden Kasten mit dem Punkt auf der Skala, der Ihren heutigen Gesundheitszustand am besten wiedergibt.

Ihr heutiger
Gesundheitszustand



Wir bedanken uns herzlich für Ihre Mitarbeit und bitten Sie um eine kurze Bewertung des Fragebogens

War der Fragebogen einfach oder schwierig auszufüllen? Bitte kreuzen Sie die Skala entsprechend an:

Einfach auszufüllen ←――――――――――――→ Schwierig auszufüllen

|__| |__| |__| |__| |__| |__|
1 2 3 4 5 6

Wie beurteilen Sie die Länge des Fragebogens? Bitte kreuzen Sie wieder die Skala entsprechend an:

In Ordnung ←――――――――――――――――→ Viel zu lang

|__| |__| |__| |__| |__| |__|
1 2 3 4 5 6

Wie viel Zeit haben Sie zum Ausfüllen des Fragebogens gebraucht?

________________ Minuten

Haben Sie noch Anmerkungen zum Fragebogen?

____

____

____

____

Herzlichen Dank!

Attachment IV

Probanden-ID: ________________ Datum: ____________ Interviewer-ID: ___________

Behandlung des Diabetes

1. **Werden Sie <u>gegenwärtig</u> mit blutzuckersenkenden Tabletten behandelt?** (z.B.: Metformin, Amaryl, Glimepirid, Januvia, Eucreas, Galvus, Euglucon, Onglyza, Avandia, Actos)

|__| Nein |__| Ja, und zwar:

Name der Tabletten (bitte geben Sie die genaue Bezeichnung an, dabei sind auch die Zahlen nach dem Namen wichtig z.B. „Glibenclamid 3,5“)	**Zahl der Tabletten pro Tag**	**Seit wann nehmen Sie das Medikament ungefähr ein?**
1.		
2.		
3.		
4.		
5.		
6.		

2. **Gab es <u>in den letzten 6 Monaten</u> Änderungen hinsichtlich der Behandlung mit blutzuckersenkenden Tabletten (z.B. Tabletten neu verordnet, abgesetzt oder die Dosis geändert)?**

|__| Nein |__| Ja, und zwar:

Name der Tabletten	**Art der Änderung**	**Zeitpunkt der Änderung**
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________

3. Werden Sie gegenwärtig mit Insulin behandelt? Gemeint sind alle kurz- und langwirksamen Insulinpräparate, die Sie verwenden.

|__| Nein |__| Ja, und zwar:

Name des Insulinpräparates (bitte geben Sie die genaue Bezeichnung an, dabei sind auch die Zahlen nach dem Namen wichtig (z.B. 100 IU).	**Art der Insulin-Zuführung**	**Einheiten pro Tag**	**Seit wann erhalten Sie das Medikament ungefähr?**
	|__| Pen zum Füllen mit Patronen |__| Fertig-Pen (Einweg; wenn leer, wird er weggeworfen) |__| Herkömmliche Injektionsspritze |__| Insulinpumpe		
	|__| Pen zum Füllen mit Patronen |__| Fertig-Pen (Einweg; wenn leer, wird er weggeworfen) |__| Herkömmliche Injektionsspritze |__| Insulinpumpe		
	|__| Pen zum Füllen mit Patronen |__| Fertig-Pen (Einweg; wenn leer, wird er weggeworfen) |__| Herkömmliche Injektionsspritze |__| Insulinpumpe		

Probanden-ID: ________________ Datum: ____________ Interviewer-ID: ___________

4. Gab es in den letzten 6 Monaten Änderungen hinsichtlich ihrer Insulintherapie?

|__| Nein |__| Ja, und zwar:

Name des Insulinpräparates	Art der Änderung	Zeitpunkt der Änderung
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________
	|__| Neu verordnet |__| Abgesetzt |__| Dosis reduziert |__| Dosis erhöht	seit _________ seit _________ seit _________ seit _________

5. Wird Ihr Diabetes gegenwärtig mit anderen als den bisher erfragten Medikamenten behandelt?

(Hier bitte keine Medikamente gegen andere Erkrankungen angeben - diese werden später abgefragt)

Name des Medikaments (bitte geben Sie die genaue Bezeichnung an, dabei sind auch die Zahlen nach dem Namen wichtig)	**Art des Medikaments (z.B. Tabletten, Spritzen)**	**Tagesdosis (z.B. Anzahl Tabl. pro Tag, Anzahl Spritzen pro Tag)**	**Seit wann erhalten Sie das Medikament ungefähr?**

Medikamente gegen andere Erkrankungen

6. Welche Medikamente nehmen die Sie gegenwärtig zusätzlich zu Ihrer Diabetes-Therapie REGELMÄSSIG ein?

(Die Medikamente, die Sie nur bei Bedarf nehmen, werden später abgefragt)

|__| Ich nehme zurzeit keine weiteren Medikamente ein

|__| Ich nehme zurzeit folgende weiteren Medikamente ein

Bitte versuchen Sie die Angaben so genau wie möglich zu machen!

Name des Arzneimittels und Dosierung (bitte geben Sie die genaue Bezeichnung an, dabei sind auch die Zahlen nach dem Namen wichtig)	**Darreichungsform (Tabletten, Tropfen etc.)** ,	**Tagesdosis** z.B. 2 mal pro Tag	**Häufigkeit der Einnahme**	**Seit wann nehmen Sie das Medikament ungefähr ein?** z. B. seit … Monaten oder … Jahren
				seit _________
				seit _________
				seit _________
				seit _________
				seit _________
				seit _________
				seit _________

Probanden-ID: ________________ Datum: ____________ Interviewer-ID: ___________

7. Gibt es <u>weitere Medikamente,</u> die Sie <u>in den letzten 6 Monaten</u> NACH BEDARF genommen haben?

|__| Nein |__| Ja, und zwar:

Name des Arzneimittels (bitte geben Sie die genaue Bezeichnung an, dabei sind auch die Zahlen nach dem Namen wichtig)	**Darreichungsform (Tabletten, Tropfen etc.) und Tagesdosis** z.B. „Tabletten 50 mg, 2 mal pro Tag“	**Wie häufig in den letzten 6 Monaten?**
		Etwa ______Tage
		Etwa ______Tage
		Etwa ______Tage
		Etwa ______Tage
		Etwa ______Tage
		Etwa ______Tage

*Bitte tragen Sie ein Fragezeichen ein, falls Sie sich bei der Dosierung unsicher sind

8. Abschließende Rückfrage: „Und ansonsten nehmen Sie zur Zeit keine weiteren Medikamente mehr ein? Z.B. auch keine Vitamine, Johanniskraut, homöopathische Präparate, irgendwelche Salben…?“

9. Wie viel haben Sie für den Kauf alle Ihrer <u>verschreibungspflichtigen</u> Medikamente in den <u>letzten 6 Monaten</u> selbst aufgewendet, inklusive Ausgaben für Rezeptgebühren? Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte:

_______€.

|__| Gar nichts, weil |__| befreit bzw. |__| privat versichert

|__| „weiß ich nicht“

10. Wie viel haben Sie für den Kauf alle Ihrer <u>rezeptfreien</u> Medikamente in den <u>letzten 6 Monaten</u> selbst aufgewendet? Falls Sie den Betrag nicht genau nennen können, schätzen Sie ihn bitte:

_______€.

|__| Gar nichts

|__| „weiß ich nicht“

Danksagung

An dieser Stelle möchte ich all denen danken, die zum Gelingen dieser Arbeit beigetragen haben.

Zuerst möchte ich mich bei Frau Prof. Dr. med. Dr. P.H. Andrea Icks, die diese Arbeit in vielerlei Hinsicht erst ermöglichte, für die Betreuung der Arbeit und Ihre immer gewährte Unterstützung bedanken.

Mein besonderer Dank gilt Herrn Prof. Dr. med. Heinz-H. Abholz und Herrn Dr. med. Matthias Kaltheuner dafür, dass sie die Durchführung der Patienteninterviews in den Räumen ihrer Praxen ermöglicht und wohlwollend unterstützt haben.

Abschließend danke ich meiner Familie für ihre Unterstützung, Geduld und Nachsicht, die mir bei der Entstehung diese Arbeit sehr geholfen haben.

Eidesstattliche Erklärung

Hiermit versichere ich an Eides statt, dass ich

1) diese Arbeit selbstständig und ohne unerlaubte fremde Hilfe angefertigt habe,
2) keine anderen als die von mir angegebenen Quellen oder Hilfsmittel benutzt habe und
3) die den benutzten Werken wörtlich oder inhaltlich entnommenen Stellen als solche kenntlich gemacht habe.

Außerdem erkläre ich, dass ich keine weiteren Promotionsversuche unternommen habe.

....

Ort, Datum Unterschrift