Quality criteria/key components for high quality of diabetes management to avoid diabetes-related complications

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Abstract

Aim The aim of this review should be to map data and to identify quality indicators for good practices for diabetes management and secondary prevention, specifically of type 2 diabetes.

Methods To achieve this aim we performed the following steps: (i) a literature review on evaluation criteria, (ii) selection of quality criteria and key components for high quality of care, (iii) creation of a checklist to identify the best practice of diabetes management based on the detected criteria.

Results The literature search about the quality indicators for diabetes care resulted in the following: identifying of key components and quality indicators for structure, process and outcome quality.

Conclusions The set of quality criteria will be discussed and used to identify the best practice diabetes management programs for secondary prevention of type 2 diabetes.

Keywords Type 2 diabetes · Secondary prevention · Disease management · Quality indicators · Key components

Background

Diabetes mellitus is an important factor in increasing risk for secondary vascular diseases such as cardiovascular, renal, and eye complications (Pathak et al. 2019). Risk factors and outcomes vary across countries, reflecting a mixture of genetic background, societal, and cultural factors, as well as public health politics, in combination with local quality of health care (EUCID 2008).

Effective as well as efficient diabetes management is an essential component to prevent or delay the complications and comorbidities of diabetes mellitus (Rothe et al. 2008). There is evidence available that cardiovascular and diabetes specific complications can be stopped or reduced as a result of good diabetes management (Hunter and Fairfield 1997; Rothe 2010; Schäfer et al. 2010b). The disease management approach to patient care seeks to coordinate resources across the healthcare delivery system. The growing interest in evidence-based medicine and outcomes, and a commitment to integrated care across the primary, secondary, and community care sectors, all contribute to making disease management an attractive idea. A combination of patient education, provider use of practice guidelines, appropriate consultation, and supplies of drugs and ancillary services all come together in the disease management process (Hunter and Fairfield 1997). Disease management views patients as entities experiencing the clinical course of a disease, rather than viewing their care as a series of discrete episodes or as fragmentary encounters with different parts of the healthcare system. It has four parts according to Hunter and Fairfield (1997):

1) a knowledge base (guidelines)
2) an integrated care delivery system without boundaries between medical specialities and institutions
3) a continuous quality improvement process, and
4) patient empowerment.

Nevertheless, a still better way — innovative and patient-centered — to reach good quality of care and to avoid complications also for multimorbid patients with type 2 diabetes (T2DM) is the Chronic Care Model (Coleman et al. 2009; Wagner et al. 2001) based on six core elements:

1) delivery system design (e.g., integrated)
2) organizational support
3) decision support (e.g., based on complex practice guidelines)
4) clinical information system (for longitudinal patient monitoring)
5) self-management support (to enhance patient empowerment), and
6) community resources.

**Aim**

The aim of this review was to map data and to identify quality indicators for good practices for diabetes management and secondary prevention, specifically of T2DM. Secondary prevention of diabetes relies on early detection of (pre-)diabetes (e.g., through screening) and application of intervention strategies and disease management to prevent the progression of the disease. Therefore, all (primary) preventions of the secondary diseases (e.g., diabetes specific complications and co-morbidities) of T2DM are involved, according to Last (2001).

Table 1 Indicators for structure quality

| 1. Complex cross-sectoral diabetes practice guidelines for patients with multiple chronic diseases (e.g., MVS) available |
| • with criteria for in time/early transfer to the next care level |
| • with rules/standards for cooperation between the care level and integrated care, resp. |
| • with risk adjusted therapeutic targets |

| 2. Cross-sectoral and population based care (interfaces, pathways, integrated care) |
| • cooperation of interdisciplinary working practice teams → bottom up programs! |

| 3. Cross-sectoral continuous quality management of physicians, outcome-oriented! |
| • regularly evaluation of the outcome of the management program/care model |
| • regularly feed-back reports to the physicians |
| • longitudinal monitoring of patients/ telemedicine |

| 4. Patient centered approach → to raise the value for the patient (value based health care) |
| • patient empowerment programs |
| • shared decision making of physician and patient |
| • risk assessment and stratification, respectively → identification of homogeneous groups of patients (by risk adjusted therapeutic targets) |
| • prioritization of therapeutic elements for patients with multiple chronic diseases/ conditions |
| • early diagnosis of multimorbidity (50+) → early therapy → secondary prevention |

→ Participating rate of patients!
Recently, evaluation criteria have been needed to identify key components of high quality of care (Martirosyan et al. 2010). Therefore, quality criteria were developed by several associations, e.g., by the American Diabetes Association (ADA 2014) and the European Association for the Study of Diabetes (EASD) (Rydén et al. 2013).

The key components as results of this review are to identify the important quality indicators and control points for better diabetes management, with the final goal of reducing the risk factors for endpoints, such as high plasma glucose, high blood pressure, and dyslipidemia — all components of the metabolic (vascular) syndrome (MVS). The MVS is recognized as an important precondition for both T2DM and cardiovascular diseases. MVS already describes a cluster of risk factors [overweight, elevated/decreased blood lipids, elevated blood pressure, (pre-)diabetes] as well as when detected late or when far progressed — the common presence of different manifest diseases (such as intra-abdominal obesity, dyslipidemia, hypertension, T2DM) (Alberti et al. 2009; Hanefeld et al. 2007; Kwasny et al. 2017).

### Methods

With the goal of identifying the appropriate disease management programs for the European Union in the future, we developed the quality criteria in several steps:

1) a literature review on evaluation criteria
2) selection of quality criteria and key components for high quality of care
3) creation of a checklist to identify the best practice of diabetes management in Europe based on the detected criteria.

We performed a literature search with regard to the quality indicators, and were subsequently able to find out the key components for structure, process, and outcome quality of diabetes care.

### Table 2  Indicators for process quality

| Percentage of patients with regular self-management of: | Percentage of patients with quarterly examination of: | Percentage of patients with annual examination of: | Percentage with regular education: |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| • Plasma glucose (FPG + p.p. PG): OAD: e.g., 2 x /week | • HbA1c | • Lipid parameters | Refresher courses every 3 years |
| CT: e.g., 3 x /week | • Body weight/BMI | • Uric acid | |
| ICT: e.g., 3–4 x /week | • Blood pressure | • Creatinine | |
| • Day–night profile: Insulin therapy: e.g., 2 x monthly | • Foot inspection | • Albumin i. U. | |
| (uUrine glucose self-monitoring is not necessary!) | • Documentation of findings | • Foot pulses and vibration (tuning fork) test | |
| • Blood pressure (RR) | | • Clinical examination | |
| • Weight | | • ECG + 24 h RR profile | |
| | | • Ocular fundus | |
| | | • Internal quality management | |

### Table 3  Indicators for outcome quality — intermediate outcome indicators

| Percentages (%) of patients with the following parameters under/above a target |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Indicator | For example: | | |
| BMI | < 30 kg/m² | | |
| Waist circumference | < 102 cm (males) | | |
| | < 88 cm (females) | | |
| Triglycerides | < 1.7 mmol/l (< 150 mg/dl) | | |
| HDL-C | > 1.1 mmol/l (males) (> 43 mg/dl) | | |
| | > 1.3 mmol/l (females) (> 50 mg/dl) | | |
| LDL-C | < 2.6 mmol/l (< 100 mg/dl) | | |
| Blood pressure (RR) | < 140/90 mmHg | | |
| HbA1c | < 7.0% | | |
| | (< 53 mmol/mol) | | |

Legend: HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol

### Table 4  Long-term and terminal outcome indicators

| Incidence rates |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| • Diabetic foot syndrome (DFS) rate | • Major limb amputation rate (only after-effects of DFS) | • Myocardial infarction rate | |
| | • Stroke rate | • Cardiovascular mortality rate | |
| | • Retinopathy (RP) rate | • Blindness rate (only after-effects of RP) | |
| | • Nephropathy (NP) rate | • Dialysis rate (only after-effects of NP) | |
| | • Uremia mortality rate | | |
### Table 5 Checklist for a good diabetes management program

| Element | Yes | No | Unknown |
|---------|-----|----|---------|
| **Criteria for structural quality** |     |    |         |
| Diabetes management program available? |     |    |         |
| Chronic care program available? |     |    |         |
| Program has been developed bottom up? |     |    |         |
| High participating rates of physicians? |     |    |         |
| Guidelines for patients with DMT2 are on a scientific basis? | (cross-sectoral with criteria for in time/early transfer to the specialized care level, with rules/standards for interdisciplinary cooperation, with risk adjusted therapeutic targets) |     |         |
| Complex guidelines for patients with DMT2 and multiple chronic conditions are available? | (cooperation of interdisciplinary working practice teams with described pathways, with involvement of GP’s, diabetes specialists, specialized hospitals, specialized nurses, specialists for diabetic complications) |     |         |
| Integrated care structure? | (cross-sectoral, regularly feed-back reports to the physicians, longitudinal monitoring/telemedicine, evaluation of the outcome of the management program) |     |         |
| Outcome-oriented quality management? | (high participating rate of patients, value based health care, patient empowerment, shared decision making, risk assessment and stratification, early diagnosis of multimorbidity with secondary prevention, prioritization of therapeutic elements) |     |         |
| Patient-centered approach? |     |    |         |
| **Criteria for process quality** |     |    |         |
| Regular self-management? | (blood glucose self-check, day-night-profile, urine glucose self-monitoring, blood pressure self-check, weight self-checks) |     |         |
| Quarterly examinations? | (HbA1c, body weight, blood pressure [RR], foot inspection, documentation of findings) |     |         |
| Annual examinations? | (lipid parameters, uric acid, creatinine, albumin i. U., foot pulses and vibration sensation test (tuning fork test), clinical examination, ECG+ 24 RR profile, ocular fundus, internal quality management) | (refresher courses) |         |
| Regular education? |     |    |         |
| Hospitalization rates of patients? |     |    |         |
| **Criteria for intermediate outcome quality** |     |    |         |
| Quality of life → QALY? | (quality-adjusted life year) |     |         |
| Weight reduction? | (by ca. 5%) |     |         |
| Waist circumference reduction? | (e.g., males < 102 cm, females < 88 cm) |     |         |
| TG reduction? | (e.g., < 1.7 mmol/l; < 150 mg/l) |     |         |
| HDL-C rising? | (e.g., males > 1.1 mmol/l or > 43 mg/dl; females > 1.3 mmol/l or > 50 mg/dl) |     |         |
| LDL-C reduction? | (e.g., < 2.6 mmol/l or < 100 mg/dl) |     |         |
| Blood pressure reduction? | (e.g., < 140/85 mmHg) |     |         |
| HbA1c reduction? | (e.g., < 7%) |     |         |
| **Criteria for longterm outcome quality** |     |    |         |
| Major limb amputations reducing? |     |    |         |
| Myocardial infarction rates reducing? |     |    |         |
| Stroke rates reducing? |     |    |         |
| Cardiovascular mortality rates reducing? |     |    |         |
| Microangiopathy rates reducing? | (nephropathy or dialysis, retinopathy or blindness, neuropathy or diabetic foot syndrome) |     |         |
| **Cost-effectiveness of the management program** |     |    |         |
| Pay for performance? |     |    |         |
| Pay for outcome? |     |    |         |
| Other incentive? |     |    |         |

FPG = fasting plasma glucose; p.p. = postprandial; OAD = oral antidiabetic drugs; CT = conventional insulin therapy; ICT = intensified conventional insulin therapy; ECG = electrocardiogram
MEDLINE was searched via PubMed using the following search strategy:

[(structure OR process OR outcome) AND (quality indicators OR key components)] AND (type 2 diabetes).

We applied the following PubMed limits in order to increase the specificity of our search: (“humans”[MeSH Terms]).

Additionally, we scanned congress proceedings and reference lists of relevant articles, and searched our own archive for further potentially relevant publications, not identified through the electronic search.

Subsequently, we extracted quality indicators for structure, process, and outcome quality. These quality indicators and key elements should become the scientific basis for identifying the best practice for diabetes management and secondary prevention.

Results

Literature review

To identify quality criteria and key components for high-quality care for people with T2DM, in total 125 publications were searched (see Figure 1). Quality criteria for high-quality care were finally selected from 33 essential publications.

Selection of the quality criteria and key components

After the search strategy, inclusive limitations and screening of abstracts and papers, key components for quality on structure (Greenhalgh 1994; Hunter and Fairfield 1997; Rijkens et al. 2012; Rothe 2010; Rothe et al. 2008) (see Table 1), process (Bodicoat et al. 2014; Burgers 2010; Coppell et al. 2011; Correa-de-Araujo et al. 2006; Doubova et al. 2013; Gandjour et al. 2002; Grinjsova et al. 2014; Guthrie et al. 2003; Guthrie et al. 2005; Pedersen and Jacobsen 2011; Schulze et al. 2009) (see Table 2) and outcome-level (Bodicoat et al. 2014; Elissen et al. 2012; Fung et al. 2012; Grinjsova et al. 2014; Guthrie et al. 2003; Hermans et al. 2013; Liu et al. 2010; Marley et al. 2012; Nobels et al. 2011; Pajunen et al. 2010b; Schäfer et al. 2010a; Schulze et al. 2009; Schunk et al. 2011; Sidorenkov et al. 2013a; b; Voorham et al. 2008; Wee et al. 2008) were identified and suggested.

Quality of life is also important for the outcome of diabetes care (Sundaram et al. 2007; Wens et al. 2007).

Intermediate outcome indicators (see Table 3) can be measured easily, were often called “surrogate parameters” and are in concordance to the therapeutic targets for patients with DMT2 and with MVS.

Long term outcome indicators (see Table 4) (Bodicoat et al. 2014; Guthrie et al. 2005; Lix et al. 2013; Lopez-Lopez and Gutierrez-Soria, 2012; Sidorenkov et al. 2013a; Wens et al. 2007) are the so called “endpoints” of the natural history as well as of the clinical course of the disease.

Finally, a checklist for identifying the best practice of diabetes management was created (see Table 5).

Conclusions

Several projects aiming to enhance reporting related to diabetes care quality have been already conducted in the past. For example, the European Core Indicators for Diabetes Mellitus (EUCID) (EUCID 2008) project developed 27 indicators and demonstrated the feasibility of data collection in different EU countries and future member states. Some consortia have developed quality indicators specifically for clinical diabetes care. The EUBIROD network, for example, has been created for continuous monitoring of quality of care through the production of series of indicators with a special methodology and to build up a common European infrastructure for standardized information exchange in diabetes care, for the purpose of monitoring, updating, and disseminating evidence on the application and clinical effectiveness of best practice guidelines on a regular basis (Benedetti et al. 2009).

The published quality indicators so far are quite different for structure quality, but quite similar for process and outcome quality. Comparisons between countries would be difficult where different standards are used in guidelines, as well as for measurements. Therefore, common statements/recommendations of ADA together with EASD have been published (Inzucchi et al. 2012; Rydén et al. 2013). Unified quality standards are necessary for a systematic evaluation and reporting of diabetes management programs (Pajunen et al. 2010a; Willmeroth et al. 2019). Nevertheless, it is unclear if the needs of people with diabetes are finally met. People with diabetes have to deal with many tasks that are associated with a chronic disease. Access to health care service plays a major role in primary diabetes care. Problems can result from perceived and real barriers, and lead to poorer health outcomes (Zgibor and Songer 2001). Therefore, in addition to the need of identifying the best programs, patient needs and barriers should be also taken in consideration in the context of the programs (Kuske et al. 2013; Rothe 2010).

Nevertheless, it is unknown up to now what the best practice — for the best outcome — is. The collected and selected set of quality criteria will be used to identify best-practice diabetes management programs on secondary prevention of T2DM throughout EU member states in the future. The results will be used; how successful intervention strategies could be transferred and implemented elsewhere, and how to try to influence the policies towards improvement of diabetes care and management.
Therefore, in a further step we will prepare a systematic review about existing diabetes management programs in Europe based on these selected quality criteria and created checklist.

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**Compliance with ethical standards** The paper meets ethical standards. An ethical assessment is not necessary since this is only an (literature) review without any patient data.

**Conflict of interest** There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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