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PATIENT REPORTED OUTCOMES IN ELDERLY PATIENTS WITH DIABETES MELLITUS TYPE 2 IN SLOVENIA
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Abstract

The aim of this thesis was to measure patient reported outcomes, such as health related quality of life and general diabetes knowledge of elderly diabetes mellitus type 2 (DMT2) patients in Slovenia. Patient reported outcomes demonstrate patient perspectives when evaluating the delivery of care. In Slovenia, a new, multidisciplinary model of chronic care was introduced in 2011, which yet needs to demonstrate the efficiency, care improvement and cost reduction. Thus, another aim of the study was to research if multidisciplinary teams in diabetes care are economically viable.

To achieve the above, the study was divided into 4 subprojects. Firstly, the general level of diabetes knowledge of elderly DMT2 patients (n=179) was measured. Secondly, the reliability and validity of generic, European Quality of Life-5 Dimensions (EQ-5D), and disease specific, Audit on Diabetes Dependent Quality of Life (ADDQoL) instruments were examined. Thirdly, health related quality of life of elderly diabetic patients (n=285) was assessed. Fourthly, the systematic literature review on the cost-effectiveness of multidisciplinary teams was conducted.

The data were collected during the period 2011–2012.

The main contributions of the current thesis can be summarised as follows: This was the first study to measure general diabetes knowledge of elderly DMT2 patients in Slovenia. The results showed that the place of living does not have an impact neither on diabetes knowledge nor the health related quality of life of these patients.

Secondly, a pioneering example of measuring health related quality of life (HRQoL) in elderly diabetic patients in Slovenia, using a validated and reliable instrument (ADDQoL) was provided. A study to evaluate the relationships between diabetic and other co-existing chronic medical conditions on health related quality of life was performed. As part of that study, the reliability and validity of the instruments (EQ-5D and ADDQoL) were measured, and the analysis showed that both instruments are reliable. Thirdly, a systematic way of finding evidence for understanding the cost-effectiveness of multidisciplinary teams was applied. The results of the literature review show weak improvements in the economic outcomes.

In general, the thesis contributes to the improved understanding of patient reported outcomes in elderly diabetic patients, which can be a measure in assessing diabetes care program in Slovenia, and offers a basis for a national evaluation of the Model Practices. Furthermore, patient reported outcomes of elderly diabetic patients is important to Slovenian decision makers to identify and implement appropriate interventions for achieving better management of diabetes and ultimately improving the quality of life of diabetes patients.

Keywords: Audit of Diabetes Dependent Quality of Life (ADDQoL), Diabetes mellitus type 2 (DMT2), elderly, EQ-5D, health related quality of life (HRQoL), patient education, Patient reported outcomes
Turk, Eva, Ikääntyvien tyypin 2 diabetes potilaiden ilmoittamat hoitotulokset Sloveniaassa.

Tulostettu teksti:

Tiivistelmä


Tutkimus jaettiin neljään osaprojektiin.

Ensinnä mitattiin ikääiden tyypin 2 diabetespotilaiden (n=179) yleistä diabetestietämystä. Toiseksi selvitettiin geneerisen European Quality of Life- 5 Dimensions- (EQ-5D) ja diabeteskohdtaisen ADDQoL -mittarin luotettavuus ja validiteetti. Kolmanneksi arvioitiin ikääiden diabetespotilaiden (n=285) terveyteen liittyvää elämänlaatua. Neljänneksi tehtiin moniammatillisten tiimien kustannus-tehokkuutta koskeva systemaattinen kirjallisuuskatsaus.


Tulokset voidaan tiivistää seuraavasti:

Kyseessä oli ensimmäinen tutkimus, jossa mitattiin ikääiden tyypin 2 diabetespotilaiden yleistä diabetestietämystä Sloveniassa. Tulosten mukaan asuinpaikka ei vaikuta potilaiden diabetestietämystään tai terveyteen liittyvään elämänlaatuun.

Toiseksi, Sloveniassa toteutettiin pioneerihanke, jossa mitattiin ikääiden potilaiden terveyteen liittyvää elämänlaatua (HRQoL) validoidun ja luotettavan instrumentin (ADDQoL) avulla. Tutkimuksessa selvitettiin diabeteksen ja muiden pitkäaikaissairauksien yhteisvaikutusta terveyteen liittyvään elämänlaatuun. Osana tutkimusta selvitettiin instrumenttien (EQ-5D ja ADDQoL) luotettavuus ja validiteetti. Molemmat osoittautuivat luotettaviksi.

Kolmanneksi, tutkimuksessa esittiin systemaattisesti näyttöä moniammatillisten tiimien kustannustehokkuuden arvioimiseksi. Kirjallisuuskatsauksen mukaan taloudellinen tulos paranee vain vähän.

Tutkimus lisää tietoa potilaiden ilmoittamista tuloksista ikääiden diabetespotilaiden kohdalta, mitä voidaan käyttää diabeteshoidon arvioinnissa Sloveniassa sekä mallikäytäntöjen kansallisen arvioinnin perustana. Diabetespotilaiden itse ilmoittava terveystieto on Slovenian päätöksenteoksi käytettävä sopivien interventioiden löytämisessä ja toteuttamisessa, kun halutaan parantaa diabeteshoidon ja potilaiden elämänlaatua.

Asiasanat: Audit of Diabetes Dependent Quality of Life (ADDQoL), EQ-5D, ikääät, potilaan ohjaus, potilaiden ilmoittamat tulokset, terveyteen liittyvä elämänlaatu (HRQoL), tyypin 2 diabetes (DMT2)
Acknowledgements

Of all of the pages written, this is the most important one.

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offering me a safe haven when my seas were rough. I know it was not always easy. You truly are the people I look up to.
**Abbreviations**

95 % CI  95 % Confidence Interval  
ADDQoL  Audit of Diabetes Dependent Quality of Life  
AWI  Average Weighted Impact  
CCM  Chronic Care Model  
DMT1  Diabetes Mellitus Type 1  
DMT2  Diabetes Mellitus Type 2  
EQ-5D  European Quality of Life – 5 Dimensions  
EU  European Union  
GDP  Gross Domestic Income  
GP  General Practitioner  
HbA1c  Glycated hemoglobin  
HRQoL  Health Related Quality of Life  
HTA  Health Technology Assessment  
ICER  Incremental Cost-Effectiveness Ratio  
IDF  International Diabetes Federation  
LY  Life Years  
MDKT  Michigan Diabetes Knowledge Test  
MP  Model Practice  
OECD  Organisation for Economic Co-operation and Development  
OR  Odds Ratio  
PROMs  Patient Reported Outcome Measure  
QALY  Quality Adjusted Life Years  
QoL  Quality of Life  
RN  Registered Nurse  
SD  Standard Deviation  
THE  Total Health Expenditure  
VAS  Visual Analogue Scale  
WHO  World Health Organization
List of original publications

This thesis is based on following publications which are referred to in the text by their Roman numerals I–IV:


III Turk E, Prevolnik Rupel V, Tapajner A & Isola A Reliability and validity of the Audit on diabetes-dependent quality of life (ADDQoL) and EQ-5D in elderly Slovenian diabetic patients. Manuscript.

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1 Introduction and aim of the thesis

Diabetes mellitus type 2 (DMT2), a chronic metabolic disease, characterised by high levels of glucose in the blood, is a matter of global concern and it has moved up on the health policy agenda over the past decades (Whiting et al. 2011; World Health Organisation 2011; International Diabetes Federation 2012). The Organisation for Economic Co-operation and Development (OECD) reports that diabetes was the principal cause of death of more than 100,000 persons in the European Union (EU) in 2008, and is the within the top five leading causes of death in most developed countries (Organisation for Economic Co-operation and Development 2010).

There are around 33 million people with diabetes mellitus in the EU (Organisation for Economic Co-operation and Development 2010), and according to the International Diabetes Federation (IDF) Atlas (Whiting et al. 2011), in the European region, 52.8 million people are affected by diabetes. Of those, DMT2 accounts for 85–95 percent of all cases. Furthermore, it is generally accepted that 50 percent of all people with diabetes are unaware of their condition and studies estimate that DMT2 may be present for on average seven years prior to diagnosis. The prevalence of DMT2 is increasing due to a number of reasons including lifestyle factors such as low physical activity and obesity (International Diabetes Federation Europe 2008). To a large degree the high prevalence of type DMT2 and impaired glucose tolerance (IGT) is a consequence of the ageing of the region’s population. The ageing of the society brings several specific problems. The increasing number of chronic conditions and co-morbidities, and the large numbers of drugs used per patient have a major impact on the health systems (Patterson et al. 2012).

Age is an important risk factor for DMT2. In the EU, it affects around 17 percent of elderly people (people aged 65 and over), while the number increases to 30 percent in the USA (Centers for Disease Control Prevention 2011; UN DESA 2013). Evidence shows that elderly people with diabetes use primary care services more than people without it, and their medical expenditures are 2–3 times higher (Damsgaard et al. 1987; Krop et al. 1998; American Diabetes Association 2008). The management of DMT2 is complicated in elderly due to the added effects of aging on metabolism and renal function, the use of potentially diabetogenic drugs and low levels of physical activity, often accompanied by mental impairments (Kamel and Morley 2001; Marengo and Comoglio 2011). As a result, diabetes has major implications on healthcare utilization and can have a
profound effect on quality of life (QoL) in terms of social and psychological well-being as well as physical ill-health (Sinclair 2010). It is one of the most psychologically demanding of the chronic diseases, with psychosocial factors pertinent to nearly every aspect of the disease and its treatment (Cox et al. 1996; Garratt et al. 2002a). DMT2 is ranked among the leading causes of cardiovascular disease, blindness, renal failure and lower limb amputation (Norris et al. 2008).

About 75–80 percent of people with diabetes die of cardiovascular disease, the number one cause of death in Europe. People with DMT2 have a 2–4 times higher risk of coronary heart disease than the rest of the population, and their prognosis is poorer (Stevens et al. 2001). Due to complex nature of the disease it requires coordinated approaches including multidisciplinary healthcare teams that have the expertise to provide appropriate clinical and behavioural management, and explicit involvement of patients as co-producers of care, as well as high quality clinical guidelines (Nolte and McKee 2008a; Coleman et al. 2009; Nolte et al. 2009; Knai et al. 2012).

Elderly patients tend to have lower health literacy than younger cohorts, and often fail to receive coherent and patient-centred care with adequate follow-up, thereby increasing the risk of unplanned hospital stays and higher overall costs (Oxley 2009). Empowering patients to take on a meaningful role in their own care has shown benefits such as greater satisfaction with care, improvements in metabolic and psychological outcomes and quality of life (Corabian and Harstall 2001; Funnell 2004; Deakin et al. 2005; Loveman et al. 2008). To learn about DMT2 patients’ quality of life there is a need to find the most appropriate instruments to assess health related quality of life (HRQoL). There are numerous instruments available to measure quality of life in diabetes (Garratt et al. 2002a; Haywood et al. 2005), which can be used for evaluation of management of the disease.

Currently, many health systems are still built around the acute model of care, which focuses on a single episode of care (Nolte et al. 2009). However, the increase of chronic diseases challenges health policy-makers to put in place a response that better meets the needs of people with complex chronic health problems. As health systems vary across the world, each must find their own solution in finding the appropriate models of care for the chronic diseases (Nolte and McKee 2008b; Nolte and McKee 2008a; Nolte et al. 2009).

At the time of the proposal for the current thesis, no health related quality of life (HRQoL) study involving Slovenian DMT2 patients had been undertaken.
Thus, much remains to be done for HRQoL research among diabetes mellitus type 2 patients in Slovenia.

The aim of this thesis is to measure patient reported outcomes (PROM), such as health related quality of life and general diabetes knowledge of diabetes mellitus type 2 patients in Slovenia aged 65 years and over to emphasize the importance of education about the disease for better patient empowerment. Health related quality of life and diabetes knowledge will also present an evaluation method for the Model Practices (MP) as a newly introduced form of managing diabetes on the primary care level in Slovenia (Ministry of Health 2011). In addition to the above, and in line with the introduction of Model Practices for diabetes care, which are introducing the multidisciplinary approach, another aim of the study was to research if multidisciplinary teams in diabetes care are economically viable.

Health Sciences is a multidisciplinary field that combines bio-medical, psycho-social, organizational and societal aspects of health, disease and health care. In addition, it focuses on the design and evaluation of medical-technological, behavioural and organizational interventions as well as the application of that knowledge to improve health and patient centered health care, and to ultimately improve the quality of life (University of Twente 2013). Outcomes in healthcare are the ultimate validators of the effectiveness and quality of medical care (Donabedian 2005). Outcome research investigates the outcomes of healthcare practices, and is intended to provide scientific evidence relating to decisions made by all who participate in healthcare. It also incorporates patients' experiences, preferences, and values (Clancy and Eisenberg 1998).
2 Theoretical background

2.1 Literature review

In order to develop the conceptual framework, and scope of the thesis a literature review was conducted.

The aim of the literature review was to identify the existing literature on patient reported outcomes in diabetes mellitus type 2 (DMT2).

Search strategy: Papers were identified by combining searches of electronic databases (Pubmed and EMBASE), hand searches of reference lists of selected papers, and a purposive electronic search of grey literature on key websites.

The following search terms were used in different combinations: patient reported outcome measures, PROMs, health related quality of life, HRQoL, ADDQoL, Diabetes mellitus type 2, diabetes knowledge, elderly, older.

A brief procedure of electronic database search is presented in table 1.

Table 1. Procedure of electronic database search for literature review.

<table>
<thead>
<tr>
<th>Electronic database</th>
<th>Search terms</th>
<th>Hits</th>
<th>Retrieved papers after abstract screening</th>
<th>Retrieved papers after inclusion criteria and duplication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pubmed, EMBASE</td>
<td>(patient reported outcome measure*) AND diabetes mellitus type 2</td>
<td>6</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PROM AND diabetes mellitus type 2</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>HRQOL AND diabetes mellitus type 2</td>
<td>82</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>health related quality of life AND diabetes mellitus type 2</td>
<td>479</td>
<td>47</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>ADDQoL AND diabetes mellitus type 2</td>
<td>18</td>
<td>11</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>audit on diabetes dependent quality of life AND diabetes mellitus type 2</td>
<td>14</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>diabetes knowledge AND diabetes mellitus type 2</td>
<td>1927</td>
<td>98</td>
<td>35</td>
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<tr>
<td></td>
<td>diabetes knowledge AND diabetes mellitus type 2 AND elderly AND older</td>
<td>88</td>
<td>19</td>
<td>10</td>
</tr>
</tbody>
</table>

Inclusion criteria. Literature was included using following criteria:

1. The search term included in paper title, abstract or keywords.
2. Content of the abstract potentially relevant to the main concepts of this study,
3. Main text describing health related quality of life, patient reported outcomes measures and diabetes knowledge
4. English language

Search Outcome. The literature search on patient reported outcome measures (including health related quality of life and audit of diabetes dependent quality of life) resulted in 601 hits. According to inclusion criteria 43 papers on patient reported outcomes were considered in this study. The first search step of diabetes knowledge and diabetes mellitus type 2 resulted in 1927 hits. Although plenty of papers retrieved diabetes knowledge, after searching main text, 45 papers were considered. Overall 88 papers were retrieved by literature review and were linked to the study’s main concepts of the patient reported outcomes in elderly diabetes mellitus type 2 patients.

2.2 Why Diabetes Mellitus: Aetiology and epidemiology

Diabetes mellitus is a chronic disease with serious short-term and long-term consequences for the afflicted. It is a complex of diseases of abnormal metabolism, most notable hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (American Diabetes Association 2011).

According to the World Health Organization (WHO), there are two types of diabetes mellitus: type 1 and type 2 (WHO 1999).

Diabetes mellitus type 1 diabetes (DMT1) occurs when there is a severe lack of insulin in the body because most or all of the insulin-producing cells in the pancreas (the organ that produces insulin) have been destroyed. DMT1 typically appears in people aged below 40 years of age, frequently during childhood. People with DMT1 need daily insulin injections and have to watch their diet.

Diabetes mellitus type 2 (DMT2) develops when the pancreas can make some, but not enough, insulin or if there is insulin resistance. DMT2 typically appears in people over the age of 40. People with DMT2 usually start to manage their glucose levels by making changes to their diet and lifestyle. But many people with DMT2 eventually have to start taking one or more medicine and may need to use insulin. DMT2 is the most common form of diabetes affecting about 85–90 percent of individuals with diabetes (Holt et al. 2011). Diabetes mellitus currently affects about 285 million adults worldwide and it is projected to rise to 366 million in 2030 (Wild et al. 2004; Shaw et al. 2010). The most important
demographic change to diabetes prevalence across the world appears to be the increase in the proportion of people aged 65 years and over (elderly) (Wild et al. 2004). In Europe, over 50 million individuals are affected by diabetes, 90 percent of which are type DMT2 cases. The prevalence of DMT2 increases markedly with age in all populations, in the EU, it affects around 17 percent of the elderly (UN DESA 2013), while USA the number increases to almost 30 percent of those aged 65 and over (Centers for Disease Control Prevention 2011). Elderly DMT2 patients show significant excess of cognitive dysfunction, which is linked with poorer ability in diabetes self-management and greater dependency (Sinclair et al. 2000). High level of related medical co-morbidities, increased susceptibility of hypoglycaemia and impaired activities of daily living, are some of the characteristics of elderly diabetic. These contribute to increased levels of disability, which lead to heavy usage of healthcare resources and premature mortality (Sinclair 2010). Diabetes care is complex and effective delivery of it depends on close cooperation between diabetes specialists, general practitioners and registered nurses, and attention to all causes of disability and ill – health (Sinclair 2010).

Slovenia does not differ from the comparable developed countries or from EU countries with regard to prevalence of diabetes, in fact in 2009 IDF ranked it among the top 10 countries in Europe (International Diabetes Federation 2009). The National Institute of Public health (2010) estimates approximately 125,000 diabetic patients among adults (20 to 79 years). Further it is estimated that 16 percent of the population, aged 65 and over suffer from diabetes, while the percentage of diabetes at the age of 25 to 34 years is low, 0.8 percent. A recent projection of the number of DMT2 patients in the next 40 years is shown in figure 1 and it shows a high increase of DMT2 patients in the elderly group (Atanasijević-Kunc and Drinovec 2011).
In addition to a higher prevalence in elderly, there is a higher prevalence of diabetes evident in economically less developed regions in Slovenia, as shown in figure 2 (Buzeti and Gobec 2012). The prevalence of diabetes in Slovenia was estimated according to the database of out-patient prescription drugs in 2008 and the age-standardized prevalence for receiving medication was calculated (Buzeti and Gobec 2012).
As the number of elderly people with DMT2 and other chronic diseases increases in Slovenia, outcomes such as cognitive and physical disability will become greater concerns because of their implications for quality of life, loss of independence and demands on caregivers (Artnik et al. 2012).

Diabetes management will become ever more complex due to multiple chronic diseases and patients will require numerous medications, compounded by the fact that at least half of elderly diabetic adults will have a major physical or cognitive disability in addition to the DMT2. In 2010, the Ministry of health adopted the National diabetes management program (NPOSB), which presents guidance for further development of diabetes management in Slovenia.

### 2.3 Elderly patients in Slovenia

According to OECD data, in 2011, Slovenian life expectancy at birth stood at 80.1 years, just below the OECD average of 80.4. Figure 3 shows that with regard to male life expectancy, Slovenia was with 76,8 years below the OECD average, while the female life expectancy of Slovenia was above the OECD average of 83.2, namely 83.3 (Organisation for Economic Co-operation and Development 2012a).
Slovenian population is growing older due to increased life expectancy and low birth rate, changing of cultural, health, social habits and personal development (Habjanic 2009). According to Eurostat’s population projections, Slovenia will have population of nearly 2,058,000 in 2060, with a third aged 65 years and over (SIRS; 2011). At the last census in 2002 the share of the young (0–14 years) hardly exceeded the share of persons aged 65 and over, and currently, the share of people aged 65 and over is more than 17 percent (Vertot 2009).

The tendency of decrease in the share of young population and increase in the share of elderly population in the total population is most obvious in the economically better developed regions. Figure 4 shows the increase of the population aged 65 years and over in EU and Slovenia over the past 10 years.
While life expectancy has been extended also due to improved public health and medical interventions, chronic diseases are affecting an increasing share of the elderly population, and thus the importance of the quality of life in later life has increased (Christensen et al. 2009; Kalfoss and Halvorsrud 2009). Chronic diseases become increasingly common with advancing age and this particularly applies to diabetes mellitus type 2. Around 40 percent of the population in Slovenia is overweight (Artnik et al. 2012) and the obesity rates (body mass index >30) have increased in recent decades amongst adults in Slovenia (2001: 15.0%; 2004: 14.6%; 2008: 16.2%), being higher than the average for the 29 OECD countries (15.0% in 2010) (Organisation for Economic Co-operation and Development 2010). Obesity’s growing prevalence foreshadows increases in the occurrence of health problems (such as diabetes, hypertension and cardiovascular diseases), and higher healthcare costs in the future due to the change in the demand for the healthcare services (Organisation for Economic Co-operation and Development 2012b).

2.4 Overview of the healthcare system in Slovenia

Since 1992 Slovenia has had a Bismarckian type of a social insurance system based on a single insurer for compulsory health insurance, which is fully regulated by national legislation and administered by the Health Insurance...
Institute of Slovenia (HIIS) (Albreht et al. 2009). This insurance is universal and based on a clear employment status or on a legally defined dependent status (such as minors, unemployed spouses, registered unemployed persons and persons without source of income). The entitlements associated with the healthcare system apply to public institutions or to private practitioners holding rights to provide treatment financed by public funds. The insured persons are entitled to free choice of a personal family physician at the primary level and, in the event of hospital treatment, the right to choose freely which hospital and specialist outpatient facility (Health Care and Health Insurance Act 1992). Most of the delivery of healthcare is provided through the public health service network (Health Services Act 1992).

The healthcare system is organised in three separate levels. The primary care level with healthcare centres is representing a “gatekeeper” for entering the healthcare system and is responsible for ongoing care and prevention. The secondary care level, where the patient is referred to for specialised treatment and the tertiary care level is bearing the responsibility for the advanced medical examination and treatment and development of Slovenian healthcare (Health Services Act 1992). Figure 5 presents the financial flow of the Slovenian healthcare system (Albreht et al. 2009).
Healthcare centres in Slovenia are municipality-owned providers, while other institutions, private physicians and other private service providers work on the basis of concessions. On the secondary level, there are 29 hospitals in Slovenia providing inpatient and out-patient specialist care, and 2 of them, the University clinical centre in Ljubljana and Maribor deliver tertiary health services (Albreht et al. 2010).

Total health expenditure (THE) comprises total public and private expenditure, which includes expenditure on curative care, rehabilitative care, long-term nursing care, ancillary health services, medical goods, prevention and public health services, and health administration. In 2010, the THE accounted for 8.9 percent of GDP, which is lower than the average of 9.5 percent in OECD countries (figure 6). Of this, 72.8 percent was funded by public sources (Organisation for Economic Co-operation and Development 2010; Organisation for Economic Co-operation and Development 2012b).
2.5 Care models of DMT2 patients

The management of diabetes requires a committed strategy of prevention and care (Ministry of Health 2010). Services need to be provided through an established model of service delivery (Coleman et al. 2009; Levitt et al. 2010; Bratcher and Bello 2011). Coordination of care throughout the healthcare levels (primary to tertiary) is needed to provide the full range of diabetes care (Holt et al. 2011). Communities today are challenged to scrutinize the diabetes services they offer and service delivery system model to ensure that diabetes programmes that best service clients are in place (Zwar et al. 2006; Dennis et al. 2008). As there is no particular ideal model of care, the model will take different forms or shapes in different settings and communities need to tailor their model to the needs of the clients in the community they serve.

A lot of research with regard to diabetes care has been conducted around the world, especially in high income countries, and studies show considerable variations in diabetes care (primary care, secondary care or shared systems) (Davidson et al. 2006; Levitt et al. 2010; Bratcher and Bello 2011; Jayadevappa and Chhatre 2011). In a recent meta-analysis of different diabetes care models in the US, Egginton and colleagues (Egginton et al. 2012) concluded that care management programmes for diabetes mellitus type 2 patients
accomplish limited effects on metabolic outcomes, and have unknown effects on outcomes, which are important for the patient. However, structured care of diabetic patients is associated with improved health outcomes (Renders et al. 2000; Bodenheimer et al. 2002; Doyle III 2009), and multidisciplinary teams in diabetes care have been promoted as a care approach (Wagner et al. 1996; Wagner et al. 2005; Shortus et al. 2007). According to Codispodi and colleagues (Codispoti et al. 2004), the multidisciplinary team approach ensures cooperation and coordination between disciplines to increase efficient use of resources and to improve outcomes for the patient through continuity of care. This can be achieved by ongoing, planned, community-based and patient-centered care, which consists of physicians, pharmacists, nurses, dietitians and health educators. Studies have shown the efficacy of the multidisciplinary teams (Norris et al. 2002b; Ofman et al. 2004; Bratcher and Bello 2011; Tapp et al. 2012), however evidence that multidisciplinary teams are cost-effective is still very limited (Krause 2005; O'Reilly et al. 2006; O'Reilly et al. 2007; Busse et al. 2010). A coordinated, multidisciplinary and integrated approach of diabetes care management that supports both, the patient and the health professional is required across the healthcare system (Medical Advisory Secretariat 2009a; Medical Advisory Secretariat 2009b). Research shows that there are numerous diabetes care models, which show many similarities (Zwar et al. 2006; Borrott and Bush 2008; Loveman et al. 2008; Watts et al. 2011; Egginton et al. 2012). As established by Davidson and colleagues (Davidson and Elliott 2001; Davidson et al. 2006), a healthcare model can be understood as an overarching design for the provision of a health care service, which is based on a theoretical framework, evidence based practice and clearly defined standards. The model has defined core principles and elements and a structured framework for implementation and evaluation of care. It is the decision of health policy makers whether to choose a diabetes specific model of care or to incorporate multiple chronic diseases such as diabetes, in a common chronic care model (CCM). Establishment of teams whose focus is on delivering and improving the quality of care permits the development of shared goals, defining and clarifying roles, reflecting on how care can be improved and holding each other accountable for decisions.

Recent publications by Busse and colleagues (Busse et al. 2009; Busse et al. 2010) provide strategies and interventions that policy-makers can use to tackle chronic diseases. They also present the most common integrated care models used around the globe to provide more comprehensive services.
A variety of chronic care models exist throughout the world, which outline how people with chronic conditions were to be identified and receive care according to their needs (Nolte and McKee 2008b; Nolte and McKee 2008a; Busse et al. 2009; Busse et al. 2010). One of the internationally strongest reference models (Zwar et al. 2006; Coleman et al. 2009; García-Goñi et al. 2012) is the Chronic Care Model- CCM (figure 7) developed by Wagner (Wagner et al. 1999). It is taking an explicit community or systems perspective, frequently involving comprehensive system change. The CCM consists of six components (Wagner et al. 1999):

1. Patient self-management support, which empowers and prepares patients to manage their health and health care.
2. Delivery system design, assures the delivery of evidence based effective, efficient clinical care and self-management support
3. Decision support, ensures that clinical care that is consistent with scientific evidence and patient preferences.
4. Clinical information systems, enables to organize patient and population data to facilitate efficient and effective care.
5. Organization of Healthcare, sets the framework to create a culture, organization, and mechanisms that promote safe, high-quality care.
6. Community resources, which are mobilized to meet needs of patients.

The individual components of the CCM can be incorporated in various models for chronic disease care.
Diabetes care in Slovenia is currently managed in different organisational structures, between primary and secondary level care. The trend of integrated and shared diabetes care and service delivery started shifting in 2011, when a new a new concept of healthcare delivery on the primary level was introduced: Model Practices (MP). The Model Practices are incorporating the team on the primary level, namely the general practitioners (GP) with the nursing assistants (hereinafter called health technicians) in the public health care network (Poplas Susič and Marušič 2011).

The reasoning behind the introduction of the Model Practices was mainly the shortage of GPs across the country. The Model Practices present an upgraded working manner which is founded on an integrated care approach, adhering to chronic patient treatment protocols, complete prevention, quality indicators, optimal use of laboratory services, performing optimal scope of services and procedures at primary level as well as the performance of certain activities on part of the registered nurse in accordance with their jurisdiction and responsibilities (Poplas Susič and Marušič 2011). Introducing new responsibilities to the registered nurse (RN), making her/him a more important part of the healthcare team, can contribute to the more efficient service delivery and putting the patient...
in the centre of treatment. The work organisation of the Model Practices is shown in the figure 8. While before 2011, almost all work was dedicated to acute care, and only 5 percent for prevention, the Model practices envision an equal amount of share for acute care, chronic care, nursing care and prevention. The Model Practices represent a much greater investment in diabetes awareness and prevention in diabetes management as previously. The aim of the practices is a systematic multidisciplinary diabetes management to increase quality, safety, efficiency and cost effectiveness in patient treatment by transferring the tasks to the primary level. Improved patient reported outcomes are connected with reduced healthcare utilization (Singh et al. 2005), and in order to evaluate the work of the Model Practices, patient outcomes need to be measured. This thesis focuses on patient reported outcome measures (PROMs) - health related quality of life and general diabetes knowledge.

![Fig. 8. Organisation of the primary care in Slovenia. (Poplas Susič & Marušič 2011).](image)

### 2.6 Patient reported outcomes and disease knowledge

Internationally, there has been a marked shift in thinking about what health is and how it is measured (Devlin and Appleby 2010; Devlin et al. 2010). Traditional clinical ways of measuring health and the effects of treatment are commonly accompanied patient reported outcomes (PROs). PROs as part of the Patient outcomes assessment, such as health related quality of life (HRQoL), satisfaction with care, trust, psychological well-being and utility of preferences, have the potential to play a key role in bringing the patient’s perspective and voice to the management of the disease (Curtis 1998; McHorney 2003; Wagner et al. 2005; Patrick et al. 2008). PRO is any report of the status of a patient’s health condition.
that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else (Patrick et al. 2007). PROs have been developing over the past two decades and they offer great potential to improve the quality and results of health services. They have been identified as key components of patient outcome assessment in elderly patient populations, alongside survival rates, symptoms and complications, and costs of use of resources (figure 9). In addition of providing validated evidence of health from the patient’s perspective (Patrick et al. 2008), PROs may improve the quality of interactions between health professionals and patients, and can be used to assess levels of health and need in populations (Patient reported outcome measures group 2009).

![Diagram of Patient Outcomes Assessment](image)

*HbA1C- glycated haemoglobin
*HRQoL- health related quality of life

**Fig. 9. Overview of patient outcomes assessment. (Adapted from Patrick et al. 2008).**

### 2.6.1 Patient reported outcome measures (PROMs)

Patient reported outcome measures (PROMs) can be generic or disease specific, and can produce a profile of scores relating to various dimensions of health, or a single index of health (Garratt et al. 2002a; Garratt et al. 2002b; Acquadro et al. 2003; Harrison 2004; Higgins and Green 2008). In addition to assessing levels of health and need in users of services and populations, over time they can provide
evidence of the outcomes of services for the purposes of audit, quality assurance and comparative performance evaluation (Devlin and Appleby 2010). PROMs may also improve the quality of interactions between health professionals and individual service users (Patient reported outcome measures group 2009). The movement toward informed decision making has created a need for an explicit assessment of patient preferences for treatment (Schattner et al. 2006; Corser et al. 2007; Joosten et al. 2008). Preference (or utility) is defined as levels of satisfaction, distress or desirability that people associate with particular health state. Along with clinical guidelines, patient preferences provide direction for treatment selection (van der Weijden et al. 2010).

**Health related Quality of Life**

Quality of life (QoL) is a complex multidimensional concept. WHO defines QoL as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (Whoqol Group 1994). It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment. Variables or criteria associated with a “good” QoL include good health, good social relationships, and social support. The data are inconsistent regarding a direct relationship between QoL and age (i.e., being younger rather than older), gender, functionality, marital status, and socioeconomics (Netuveli and Blane 2008).

Health-related quality of life (HRQOL) and quality of life (QoL) for this thesis were defined according to the Cochrane Handbook for Systematic Reviews of Interventions (Patrick et al. 2008) (table 2)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-related quality of life (HRQOL)</td>
<td>Personal health status. HRQOL usually refers to aspects of our lives that are dominated or significantly influenced by our mental or physical well-being</td>
</tr>
<tr>
<td>Quality of life (QoL)</td>
<td>An evaluation of all aspects of our lives, including, for example, where we live, how we live, and how we play. It encompasses such life factors as family circumstances, finances, housing and job satisfaction.</td>
</tr>
</tbody>
</table>
Given the on-going increase in numbers of people living into old age, and the associated opportunities and challenges, QoL and HRQoL become a key endpoint in identifying the life experiences of elderly people (Bradley and Speight 2002; Sinclair 2006). As such, it is of utmost importance that methodologies used in assessing HRQoL of elderly people are, in fact, assessing HRQoL and doing so reliably and validly (Speight et al. 2003).

The latest Structured Review of Patient Reported Outcome Measures for people with diabetes from Patient Reported Outcome Measurement Group reported evidence of performance for a variety of generic and disease specific patient reported outcome measures. Table 3 shows that disease specific PROMs are much more frequent than generic. The recommendations from the review suggest that combination of two measures, the European Quality of Life-5 Dimensions (EQ-5D) and a diabetes-specific measure together, provide complementary evidence of health status of people with diabetes (Patient reported outcome measures group 2009).

Table 3. Generic and disease specific PROMs. (Patient Reported Outcomes Group 2009).

<table>
<thead>
<tr>
<th>Generic</th>
<th>Disease specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36</td>
<td>Appraisal of Diabetes Scale/ADS</td>
</tr>
<tr>
<td>SF-12</td>
<td>Audit of Diabetes-Dependent Quality of Life/ADDQoL</td>
</tr>
<tr>
<td>Sickness Impact Scale</td>
<td>Diabetes 39/D-39</td>
</tr>
<tr>
<td>Health Utilities Index</td>
<td>Diabetes Health Profile/DHP</td>
</tr>
<tr>
<td>Quality of Well-Being Scale</td>
<td>Diabetes Quality of Life Measure/DQOL</td>
</tr>
<tr>
<td>EuroQoL- EQ-5D</td>
<td>Diabetes Quality of Life Clinical Trial Questionnaire/DQLCTQ</td>
</tr>
<tr>
<td>WHOQOL-BREF</td>
<td>Barriers to Physical Activity in Diabetes (Type 1) BAPADI</td>
</tr>
<tr>
<td></td>
<td>Diabetes Obstacles Questionnaire (DOQ)</td>
</tr>
<tr>
<td></td>
<td>Diabetes Treatment Satisfaction Questionnaire (DTSQs, DTSQc)</td>
</tr>
<tr>
<td></td>
<td>Diabetes Treatment Satisfaction Questionnaire for Inpatients (DTSQ-IP)</td>
</tr>
<tr>
<td></td>
<td>Diabetes Symptom Checklist-revised (DSC-R)</td>
</tr>
<tr>
<td></td>
<td>Diabetes-CAT (Computerised Adaptive Testing)</td>
</tr>
<tr>
<td></td>
<td>Diabetes Impact Survey (DIS)</td>
</tr>
<tr>
<td></td>
<td>Insulin Treatment Satisfaction Questionnaire (ITSQ)</td>
</tr>
<tr>
<td></td>
<td>Diabetes Empowerment Scale (DES)</td>
</tr>
<tr>
<td></td>
<td>Diabetes-CAT (Computerised Adaptive Testing)</td>
</tr>
<tr>
<td></td>
<td>Satisfaction with Oral Anti-Diabetic Agent Scale (SOADAS)</td>
</tr>
</tbody>
</table>

Studies have shown that diabetes mellitus type 2 individually and, especially, in combination with other chronic medical conditions considerably reduces the
health related quality of life of these patients (Bradley and Speight 2002; Hogg et al. 2012). The fact that chronic illness has a high prevalence in elderly people further emphasises the importance of appropriate assessment of HRQoL in elderly individuals (Norris 2005; Wändell 2005). Diabetes mellitus type 2 is one of the main causes of mortality, morbidity and disability in old age (Sinclair 2010). Research shows that diabetes knowledge correlates with both, diabetes specific and generic health related quality of life, indicating that diabetes knowledge might be useful as a predictor of health related quality of life when modelled properly (Xuhao 2009).

The health related quality of life of general Slovenian population is lower than in other European populations (König et al. 2005; Klemenc-Ketiš et al. 2011; Buzeti and Gobec 2012). Especially elderly people with chronic conditions and those with lower education have lower health related quality of life (Wang et al. 2008).

Measuring patient reported outcomes can present a way of implementing the needs of the patients into disease management, enabling them to share the decisions on their treatment and be involved in their own care (Patient reported outcome measures group 2009). The day to day management of diabetes is demanding and can take a heavy psychological and social toll, which may in turn result in poor control of blood glucose levels and an increased risk of complications (Wändell et al. 1997; Rubin and Peyrot 2001; Wändell 2005; Haas 2006). Issues in diabetes management in elderly people include polypharmacy, decreased cognition, deficiencies in activities of daily living, functional impairment, decreased health literacy, depression, financial problems, and increased risk of falling (Haas 2006). Therefore, in addition to clinical outcomes, patient reported outcomes and knowledge about the disease can improve the self-management as part of the diabetes management.

2.6.2 Patient disease knowledge

One of the main factors determining a chronically ill patient’s ability to cope is sufficient knowledge of the disease (Kaakinen et al. 2012). For an effective patient-health professional communication, an understanding of the patients' beliefs, attitudes and values that may influence their preferences for outcomes, and adherence to treatments, are vital (Felder-Puig et al. 2006; Joosten et al. 2008; Turk and Turk 2009). In harmony with patient reported outcomes, informed decision making is at the core of patient-centred care model, which is a process
that implies that the health professional’s knowledge is transferred to the patient, who then has the knowledge and preferences necessary to make a decision (Jayadevappa and Chhatre 2011). Patients need access to trustworthy validated information on which they can base decisions, which are made jointly with their physician (Future Hospital Commission 2013). Health literacy can be broadly defined as the ability of individuals to access and use health information to make appropriate health decisions and maintain basic health, meaning that patients possess a set of skills needed to function effectively in the health care environment (Berkman et al. 2010). It includes whether individuals can read and act upon written health information, as well as whether they possess the speaking skills to communicate their health needs to health professionals and the listening skills to understand and act on the instructions they receive (Murray 2007).

Improved health literacy can allow patients to better manage chronic conditions and to make best use of the existing health-care systems (Norris et al. 2002a; Funnell et al. 2011). Research shows that health literacy falls as age rises (Gazmararian et al. 1999; Scott et al. 2002), which means that an understanding of the implications of chronic conditions is weakest among those with the greatest need. Conventional methods of transmitting and communicating the information about the disease need to be fit for the elderly (Heisler et al. 2002; Baker and Thompson 2008). Elderly patients often experience age-related changes—both physical and cognitive. The physical changes include hearing impairment, weakening vision, and the increasing probability of multiple chronic diseases. The cognitive changes often include limited span of attention, decline in information processing speed and difficulties with understanding the technical language, as well as memory problems (Sinclair 2010).

Already in the 1990s, research has shown that people with poor health literacy show significantly less knowledge of the disease (Williams et al. 1998) and this is more common among elderly patients and patients who have low educational attainment (Council on Scientific Affairs 1999; Fransen et al. 2011). A recent systematic review (Al Sayah et al. 2012) underlines the evidence that low health literacy is consistently associated with poorer diabetes knowledge. Inadequate health literacy acts as an independent predictor of poor glycemic control and is associated with a higher prevalence of retinopathy and other self-reported complications of diabetes (Powell et al. 2007). In addition, direct association of diabetes-specific health literacy with elderly diabetic patients’ assessment of their self-care management can provide useful information for the design of effective patient intervention and/or communication strategies.
(Yamashita and Kart 2011). Disease knowledge and understanding are one of the key elements in empowering and preparing patients to manage their disease appropriately (Heisler et al. 2005). When educating the patients about the disease management, health professionals need to assess the disease knowledge and understanding of the patients (Heisler et al. 2002). A variety of tools has been developed to measure health literacy, and disease knowledge and understanding (Speight and Bradley 2001; Redman 2002; Eigenmann et al. 2009; Al Sayah et al. 2012), and table 4 provides an overview measurement tools.


<table>
<thead>
<tr>
<th>General</th>
<th>Diabetes Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Estimate of Adult Literacy in Medicine (the original REALM and the revised form REALM-R), Test of Functional Health Literacy in Adults (TOFHLA and the shorter form s-TOFHLA), Newest Vital Sign (NVS)</td>
<td>Diabetes Numeracy Test (DNT; 15-item and 43-item versions), Diabetes Specific Health Literacy Measure (DSHLM)</td>
</tr>
<tr>
<td>3-brief Screening Questions (3-brief SQ)</td>
<td>MDRTC Diabetes Knowledge test (MDKT)</td>
</tr>
<tr>
<td>3-level health literacy scale (3-level HL Scale), Single Item Literacy Screener (SILS)</td>
<td>Audit of Diabetes Knowledge (ADKnowl)</td>
</tr>
<tr>
<td>Wide Range Achievement Test (WRAT; the 3-item version WRAT-3 and the revised version WRAT-R)</td>
<td>Diabetes Knowledge Assessment</td>
</tr>
<tr>
<td>Subjective Numeracy Scale (SNS)</td>
<td></td>
</tr>
</tbody>
</table>

Based on the communication with health professionals, patients start making necessary modifications to their lifestyle (Corabian and Harstall 2001). The first step in preparing them to do so is the diabetes education and increased diabetes-specific health literacy (Funnell et al. 2011; Eckman et al. 2012; Siddiqui et al. 2012). Many patients forget much of what is said in clinic, thus educators, clinicians and nurses must recognize the need to involve patients in determining what they feel they need and address this first as a way to engage patients, and improve their retention of information, especially when dealing with elderly patients (Sinclair et al. 2000; Stiles 2011). Low medicines compliance (below 50%) by patients receiving chronic medications is frequently reported. This is often due to insufficient education and reinforcement (Sinclair 2006; Cramer et al. 2007). Effective communication between healthcare professionals and diabetic patients is the crucial indicator of successful diabetes self-management (Heisler et
Evidence shows, that increased contact time between health professionals and patients, and individual education have been associated with better glycaemic control and regimen adherence and glucose reduction (Norris et al. 2002b; Rachmani et al. 2002; Duke et al. 2009; Petek et al. 2010). Furthermore, it has been associated with reduction of healthcare costs (Christensen et al. 2004).

Individual’s specific education needs and goals have to be incorporated in the process of educating the diabetic patients (Raji et al. 2002). From this perspective, individualised instruments designed to measure individuals’ perceptions of the impact of diabetes on their QoL, may be helpful to identify individuals’ preferences, motivational deficits in diabetes management and to tailor individual treatment strategies (Wolf et al. 2005; Holmanová and Žiaková 2009). Evaluation of diabetes knowledge has served as one of the cornerstones in the overall assessment of patients with diabetes (Fitzgerald et al. 1998; Al-Qazaz et al. 2011).

To this end, patient reported outcomes such as health related quality of life, diabetes knowledge and assessments of quality of care are becoming more widely used indicators of healthcare systems, and are now commonly considered to be critical to the evaluation of the responsiveness of health systems in meeting the needs of their users (Sundaram et al. 2007; Patrick et al. 2008; Sundaram et al. 2009; Devlin et al. 2010). Namely, diabetes patients with higher levels of active self-management enjoy better health outcomes (Rubin and Peyrot 2001; Keers et al. 2005; Hollern 2011); more engaged, informed, confident, and skilled patients are more likely to perform activities that will promote their own health, and are more likely to have their healthcare needs met (Donald et al. 2012).

Empowering diabetic patients to take on a meaningful role in their own care has shown benefits such as improved communication with providers (Griffin et al. 2004), greater satisfaction with care (Golin et al. 2002), improved health outcomes (Deakin et al. 2005; Street Jr et al. 2009), as well as quality of life (Pibernik-Okanovic et al. 2004), and is therefore central to improving quality of care (Funnell et al. 2009).

2.7 Economic implications of diabetes

In high-income countries, chronic diseases, such as depressive disorder, diabetes, ischaemic heart disease and cerebrovascular disease, chronic obstructive pulmonary disease (COPD) and dementia, are among the leading contributors to
the burden of disease (Busse et al. 2010). Some studies estimate the associated costs at up to seven percent of a country’s gross domestic product (Suhrcke et al. 2006; Kanavos et al. 2012). Among those, diabetes is projected to rise further in importance during the next two decades, especially against the background of increasing levels of overweight and obesity (Finucane et al. 2011; Nolte et al. 2012a).

Chronic diseases pose a sizeable burden for national economies (Bloom et al. 2012). Diabetes mellitus type 2 is a very expensive disease (Kanavos et al. 2012). Evidence shows that patients with diabetes generate medical care costs which are two to three times higher than age-and gender-matched patients without diabetes (Gilmer et al. 1997; Gilmer et al. 2005a; O'Connor et al. 2011). Societal costs arise partly as a result of direct healthcare costs, including from healthcare utilisation, medication and potentially costly interventions, but these can also be caused by other factors, such as a decrease in work productivity. The financial cost is immense and increasing and a significant proportion of healthcare expenditure in developed countries is spent on the treatment of diabetes and its complications. The estimated annual global health expenditure for diabetes in 2007 according to Duke and colleagues (Duke et al. 2009) ranged between $232 (€178) and $422 (€324) billion, and according to (Zhang et al. 2010) it is estimated even higher, namely between $376 (€289) and $672 (€516) billion. At least one quarter is estimated to be spent in Europe and half of it in the USA (Holt et al. 2011; International Diabetes Federation 2012).

To date, no detailed economic burden of diabetes mellitus type 2 has been assessed in Slovenia. A recent estimation of direct medical costs of diabetes is that they account for almost $115 (€ 88) million (MOH, 2011). These costs include primarily the costs of providing medical services ($46 (€35) million), and prescription medicines ($34 (€26) million). The indirect costs incurred due to the effects of diabetes, such as blindness, retinal detachment, amputations, and dialyses are not included in this estimation (Health Insurance Institute of Slovenia 2012). Furthermore, intangible costs, such as pain and suffering, have not been taken into account. The Health Insurance Institute of Slovenia annually collects data on medicines use. The increase of anti-diabetic medicines in the time period 2005–2011 is shown in the table 5 (Fuerst 2012).

These costs are followed by costs for medical and technical instruments ($22 (€17) million) and compensation for temporary absence from work during the treatment of disease ($13 (€ 10) million) (Statistical Office of the Republic of Slovenia 2008; Statistical Office of the Republic of Slovenia 2011; Health
Insurance Institute of Slovenia 2012). 60 percent of the costs of diabetic care are direct costs and which present up to 15 percent of the total health expenditure (Albreht 2010). As population in Slovenia, similar to other EU countries, is ageing, in the future decades this burden can become even more serious.


<table>
<thead>
<tr>
<th>Year</th>
<th>Insulin only</th>
<th>Oral anti-diabetic products only*</th>
<th>Insulin and oral anti-diabetic products*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>13.993</td>
<td>47.510</td>
<td>8.900</td>
<td>70.403</td>
</tr>
<tr>
<td>2006</td>
<td>14.869</td>
<td>50.245</td>
<td>9.705</td>
<td>74.819</td>
</tr>
<tr>
<td>2007</td>
<td>15.663</td>
<td>52.921</td>
<td>10.596</td>
<td>79.180</td>
</tr>
<tr>
<td>2008</td>
<td>16.199</td>
<td>55.628</td>
<td>11.595</td>
<td>83.422</td>
</tr>
<tr>
<td>2009</td>
<td>16.641</td>
<td>58.858</td>
<td>12.566</td>
<td>88.065</td>
</tr>
<tr>
<td>2010</td>
<td>17.145</td>
<td>62.177</td>
<td>13.158</td>
<td>92.480</td>
</tr>
<tr>
<td>2011</td>
<td>17.572</td>
<td>65.390</td>
<td>13.792</td>
<td>96.754</td>
</tr>
</tbody>
</table>

*oral anti-diabetic products include incretin analogues

In the literature, economic outcomes are mainly defined as direct medical costs during the same time periods, and healthcare utilization (hospitalizations, and hospital admissions)(McCulloch 2000; Sidorov et al. 2002; Cranor et al. 2003; Qari 2004). Four literature reviews (Gilmer and O’Connor 2003; Gilmer et al. 2005b) were looking at various disease management programmes and their influence on economic outcomes. Some studies (Gilmer and O’Connor 2003) showed that initial costs of introducing new approaches might lead to higher costs in the first years of the program, however will occasionally start saving costs when hospitalization rates begin to decrease, and found reduced hospital expenditures, although statistically insignificant (Gilmer et al. 2005b). The authors suggest that combined stepped-care diabetes nurse case management program might provide an immediate benefit for a high-risk population.

Cobden and colleagues (Cobden et al. 2010) on the other hand found strong correlations between patient behaviours, perspectives of care, health outcomes and costs in diabetes mellitus type 2. In his research, Qari (Qari 2004) showed cost-effectiveness and time saving in achieving glycemic control when multidisciplinary (physician, dietician and diabetic educator) teamwork approach of is involved.
2.8 Summary of background

Diabetes mellitus type 2 (DMT2) is a matter of global concern and it has moved up on the health policy agenda over the past decades. The prevalence of DMT2 across the world is growing, especially among elderly population (Abdelhafiz and Sinclair 2013), and the economic burden due to complex management is affecting the healthcare budgets across the world (Dall et al. 2010; Kanavos et al. 2012). Thus an important aim in management of the elderly DMT2 patients is to provide education about the disease, in order to achieve higher empowerment and enable the patients to become active members of the diabetic care, by improving their health related quality of life.

In Slovenia, diabetes care is currently managed in different organisational structures, with different shared-care models between primary and secondary level care. They range from health centres and general practitioners (GPs) to specialised diabetic out-patient clinics. In some districts, even persons with pre-diabetes are managed at secondary level. Patients are mainly receiving care, rather than being an equal partner. This is, however, beginning to change. In 2010, a Slovene National diabetes management program (NPOSB) (Ministry of Health 2010) has been adopted and the main principles of the NPOSB are complementarity, equal access, comprehensive treatment- patient centeredness, quality, efficiency and safety, patient empowerment, partnership, continuous monitoring and respecting evidence based health practice and ensuring progress by investing in research and development of the profession. Based on these main principles, further research on diabetes care management is required. International studies have shown, that a multidisciplinary (medical doctors, nurses, health technicians, other health professionals and empowered diabetic patients) approach for managing diabetes care serves as a good example how to tackle the challenge of effective diabetes care (Codispoti et al. 2004; Doyle III 2009; Tapp et al. 2012). In 2011, the Model Practices have been introduced at the primary care level as a new concept of chronic illness management, with emphasis on diabetes (Ministry of Health 2011). The main idea is that the team of the general practitioner (GP) and health technician is joined by a registered nurse, who is responsible for monitoring health outcomes and preventive care and healthy life style modifications. The organisation of work is planned ahead and work competences are strictly defined.

Due to lack of data in Slovenia, governments, diabetes associations, health professionals and diabetic patients themselves are not aware of the health related
quality of life (HRQoL) of the diabetic patients. HRQoL and continuous education of diabetes mellitus type 2 patients, particularly elderly, about their disease, are needed in order to empower the diabetic patient. Thus, an assessment of the general diabetes knowledge of the diabetic patients is required. Neither diabetes knowledge assessment, nor the health related quality of life assessment among diabetes mellitus type 2 patients, have been carried out in Slovenia prior to this thesis.
3 Aim of the study and research questions

The aim of this thesis is to measure patient reported outcomes, like health related quality of life and general diabetes knowledge, of diabetic patients above 65 years of age. This can present a baseline for the introduction of the new Model Practices introduced as a new form of managing diabetes on the primary level in Slovenia. Furthermore, the purpose is to obtain an overview of the general knowledge about diabetes among elderly diabetic patients to emphasize the importance of education about the disease for better patient empowerment.

The study is divided in 4 Subprojects. In the Subproject 1, the general knowledge of the elderly diabetic patients in Slovenia is measured. In Subprojects 2 and 3, the patient reported outcomes are assessed and the disease specific questionnaire (ADDQol) is linguistically validated and tested for reliability and validity. In Subproject 4, in line with the newly introduced Model Practice in Slovenia, a systematic literature review of cost effectiveness of multidisciplinary teams in diabetes mellitus type 2 care has been assessed. Figure 10 shows the study process of the present thesis.

The aims and the research questions for the thesis are listed below.

Aim 1 (Subproject 1): To investigate how much the elderly diabetic patients know about the disease. Field research based on the developed Slovenian version of ‘General Diabetes Knowledge’ questionnaire was used for this aim (Paper 1).

Research questions:

a) What is the general diabetes knowledge among elderly diabetes mellitus type 2 (DMT2) patients in Slovenia?
b) What is the difference in the level of general diabetes knowledge in elderly population living in urban and rural areas?

Aim 2 (Subproject 2): To investigate the health related quality of life (HRQoL) of elderly diabetic patients in Slovenia (Paper 2)

Research questions:

a) What kind of variations in patient reported outcomes among elderly population with DMT2 are in Slovenia with regard to rural and urban areas?
b) What kind of variations in patient reported outcomes among elderly population with DMT2 are in Slovenia with regard to socio-demographic factors?
Aim 3 (Subproject 3): To examine and compare the reliability, feasibility and validity of patient reported outcome measurement (PROM) instruments among DMT2 elderly patients (Paper 3)

Research questions

a) What is the internal consistency of PROM instruments (ADDQoL and EQ-5D)?
b) What is the validity of the PROM instruments?
c) What is the feasibility of the PROM instruments?

Aim 4 (Subproject 4): To find evidence, through a systematic literature review, if multidisciplinary care of DMT2 is cost-effective (Paper 4).

Research questions:

a) Are multidisciplinary teams in diabetes mellitus type 2 (DMT2) care cost-effective?

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Fig. 10. Study process.
4 Data and methods

The overall thesis is concerned with patient reported outcomes of patients with diabetes mellitus type 2 (DMT2) in Slovenia, their disease knowledge, and the cost-effectiveness of multidisciplinary approach in diabetes care.

The internationally validated questionnaires for diabetes knowledge and patient reported outcomes, Michigan Diabetes Knowledge test (MDKT), Audit of Diabetes Dependent Quality of Life (ADDQoL), European Quality of Life-5 Dimensions (EQ-5D) were used for the thesis. Table 6 provides an overview of the instruments used, with their domain description, response options and scoring. As part of this thesis, the Audit of Diabetes Dependent Quality of Life (ADDQoL) was translated and validated in Slovenia. The linguistic validation process is described in detail in Chapter 4.2.3.

The reason for choosing the selected questionnaires for the current study was: The Michigan Diabetes Knowledge test (MDKT) is proved to be a valid and reliable instrument and easy to use knowledge scale. Developed by the Michigan Diabetes Research and Training Center, MDKT has been used in several studies to assess diabetes knowledge (Colleran et al. 2003; Murata et al. 2003; Al-Adsani et al. 2009; Al-Qazaz et al. 2011; Saleem et al. 2011).

While different measures provide complementary evidence, disease-specific tools are offering specific clinical information and reflecting treatment effects and generic measures collecting information more transferrable to the service provider and highlighting unforeseen intervention effects (Hogg et al. 2012). Based on recommendation of the PROM Group (Patient reported outcome measures group 2009), EQ-5D is considered suitable as generic measures in diabetes, and recommended for use in combination with a condition specific patient reported outcome measure. The review group is in favour of the Audit of Diabetes Dependent Quality of Life (ADDQoL) as a diabetes-specific instrument (Fitzpatrick et al. 2006; Patient reported outcome measures group 2009).
### Table 6. Overview of instruments: domains, response options, scores. (Adapted from Patient reported outcome measure group 2009).

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Domains (no. items)</th>
<th>Response options</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michigan Diabetes Knowledge test</td>
<td>14 (related to Diet, HbA1c, Hypoglycaemia management, Activity, Effect of illness and infection on blood sugar, Foot care)</td>
<td>Multiple choice</td>
<td>Ranges 0 to 14. Missing items are scored as incorrect</td>
</tr>
<tr>
<td>European Quality of Life- 5 dimensions Questionnaire (EuroQol-EQ-5D)</td>
<td>EQ-5D 5 items (Anxiety/depression Mobility, Pain/discomfort, Self-care, Usual activities)</td>
<td>EQ-5D Categorical: 3 options</td>
<td>Summation: domain profile Utility index (~0.59 to 1.00) Thermometer VAS (0-100)</td>
</tr>
<tr>
<td>Audit on Diabetes Dependent quality of life (ADDQoL)</td>
<td>19 items: Family life*, Friendships, Social life, Close personal relationship, Sex life*, Physical appearance, Physical health, Working life*, Holidays/leisure activities, Journeys, Self-confidence, Motivation, Peoples' reaction, Feelings about the future, Financial situation, Dependence on others, Living conditions, Freedom to eat, Freedom to drink)</td>
<td>Impact: -3 (very much better without diabetes) to +3 (very much worse) Importance: 0 (not at all important) to 3 (very important) 3 items with N/A option (*)</td>
<td>Impact x importance = weighted score (range -9 to +9). Scores for each item summed, then divided by number of applicable items to give average weighted impact (AWI) score (i.e. N/A items do not contribute to score).</td>
</tr>
</tbody>
</table>

Research shows that patient reported outcomes can predict healthcare utilisation in chronically ill patients (Dominick et al. 2002; Singh et al. 2005), and can be used to construct a quality adjusted life year (QALY), which is used for the cost-effectiveness studies (EuroQol Group 1990). The value set has been calculated recently in Slovenia (Prevolnik-Rupel 2007; Rupel and Ogorevc 2012). Due to previous lack of cost data of diabetes care in Slovenia, a systematic literature review was conducted to research the evidence of monetary viability of
multidisciplinary approach in chronic care elsewhere. The review shows the limited evidence in the literature, and sets the basis for the use of collecting patient reported outcomes for an economic evaluation of the newly introduced Model Practices.

4.1 Design, setting and sampling

A national diabetes registry does not exist in Slovenia; therefore the accessible population is defined as diabetic patients who visit diabetic out-patient clinics, GPs and health centres. How members of the population were accessed is described in the sampling section below.

Study Design

Two cross-sectional studies were conducted for Subprojects 1–3, using structured questionnaires. In Subproject 4, a systematic literature review was conducted.

Patient Characteristics

Descriptive statistics for patient characteristics were comprised of questions on socio-demographic characteristics (age, sex, educational level, marital status, living in own flat/house, rented flat/house, with family/nursing home and household income), self-reported health information (weight, height), and a list of conditions other than DMT2 in lay terms (hypertension, previous stroke, coronary heart disease, chronic obstructive pulmonary disease, heart failure, previous heart attack).

Sample size

According to alpha level (p-value) of 0.05, the number of predictors (degrees of freedom) of 20 and the anticipated medium effect ($f^2$) size of 0.15, in order to achieve desired statistical power level of 0.8, a sample size of $n=156$ was needed (Polit and Beck 2009).

The study was divided in two empirical parts:
In part 1 (Subproject 1), three hundred ($n=300$) questionnaires were distributed.
In part 2 (Subprojects 2 and 3), five hundred ($n=500$) questionnaires were circulated in diabetes out-patient centres across Slovenia.
Sampling

Convenience sampling was used to select the respondents in the thesis. Sampling considered known prevalence of diabetes by Slovenian regions (Buzeti and Gobec 2012). Each Slovenian community has a diabetes out-patient centre on the primary care level, thus participants living in urban areas did not have a precedence and a relatively equal ratio between participants from urban and rural area was obtained; according to demographic data approximately 50 percent of Slovenian elderly population lives in rural area (TradingEcon, 2010). There are twelve statistical regions in Slovenia (Mura, Drava, Carinthia, Savinja, Central Sava, Lower Sava, Central Slovenia, Southeast Slovenia, Inner Carniola-Karst, Upper Carniola, Gorizia, and Coastal-Karst (Statistical Office of the Republic of Slovenia 2011). As the figure 2 on page 23 shows, diabetes is more prevalent in the Eastern part of Slovenia, where people have generally lower education (Buzeti and Gobec 2012); therefore, for Subproject 1, those regions were included in the study. The only university clinical centre in Maribor with diabetologic out-patient clinic was chosen, and 2 health centres or GPs were randomly selected.

Patient reported outcomes were measured on the national level, and data were obtained from one diabetes out-patient centre in every region of Slovenia. The number of patients to conduct the questionnaire was calculated according to the population size of the region (table 7).

Table 7. Regional reach of study participants.

<table>
<thead>
<tr>
<th>Region</th>
<th>Prevalence of diabetes (%)</th>
<th>Population size</th>
<th>Number of diabetes</th>
<th>Sample/region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mura</td>
<td>6.4</td>
<td>119 537</td>
<td>7 650</td>
<td>33</td>
</tr>
<tr>
<td>Drava</td>
<td>5.7</td>
<td>322 900</td>
<td>18 405</td>
<td>78</td>
</tr>
<tr>
<td>Carinthia</td>
<td>5.5</td>
<td>72 481</td>
<td>3 986</td>
<td>17</td>
</tr>
<tr>
<td>Savinja</td>
<td>6.2</td>
<td>258 845</td>
<td>16 048</td>
<td>68</td>
</tr>
<tr>
<td>Central Sava</td>
<td>7.5</td>
<td>44 750</td>
<td>3 356</td>
<td>14</td>
</tr>
<tr>
<td>Lower Sava</td>
<td>7.3</td>
<td>69 900</td>
<td>5 103</td>
<td>22</td>
</tr>
<tr>
<td>Central Slovenia</td>
<td>5.6</td>
<td>521 965</td>
<td>29 230</td>
<td>124</td>
</tr>
<tr>
<td>Southeast Slovenia</td>
<td>5.6</td>
<td>141 166</td>
<td>7 905</td>
<td>34</td>
</tr>
<tr>
<td>Inner Carniola-Karst</td>
<td>5.7</td>
<td>51 728</td>
<td>2 948</td>
<td>13</td>
</tr>
<tr>
<td>Upper Carniola</td>
<td>5.4</td>
<td>201 779</td>
<td>10 896</td>
<td>46</td>
</tr>
<tr>
<td>Gorizia</td>
<td>5.3</td>
<td>118 533</td>
<td>6 282</td>
<td>27</td>
</tr>
<tr>
<td>Coastal-Karst</td>
<td>5.3</td>
<td>108 778</td>
<td>5 765</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>2 032 362</strong></td>
<td><strong>117 577</strong></td>
<td><strong>500</strong></td>
</tr>
</tbody>
</table>
After obtaining the permission from the heads of the out-patient centres, the questionnaire was administered while the patients were waiting to see the doctor. Patients completed the questionnaire themselves, after instructions were given by the researcher. In need of assistance, medical students, who were educated about the study protocol, explained the questions in detail to the participants who had problems with filling the questionnaire.

4.2 Instruments

The study is based on the quantitative cross-sectional surveys and a systematic literature review. The quantitative cross-sectional surveys were carried out using internationally validated questionnaires, which have been linguistically validated for the use in Slovenia.

The systematic review of the literature was based on the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.0.1.

Examples of the instruments are in the Appendix 1 and Appendix 2.

4.2.1 Michigan Diabetes Knowledge test - MDKT

In Subproject 1, the Michigan Diabetes Knowledge test was used for a cross-sectional study about knowledge regarding diabetes, risk factors, signs and symptoms, and complications among patients in North-East Slovenia with diabetes mellitus type 2, aged 65 years or older.

In order to use the MDKT, Michigan Diabetes Research Training Center (MDRTC) was asked for permission, which was obtained per e-mail, December 1, 2010. The Slovene version of the questionnaire was translated and validated. The MDKT consists of 23 knowledge test items, which represent a test of general knowledge of diabetes. The first 14 items are appropriate for people who do not use insulin (Fitzgerald et al. 1998; Redman 2002). The entire 23 items can be administered to people who do use insulin. For the purpose of this study the 14 item questionnaire was used, as one of the inclusion criteria was non-insulin dependent patients.
4.2.2 European Quality of Life-5 Dimensions (EQ-5D) and Audit of Diabetes Dependent Quality of Life (ADDQoL)

In Subprojects 2 and 3, health related quality of life (HRQoL) was assessed by two instruments, the European Quality of Life-5 Dimensions (EQ-5D) and Audit of Diabetes Dependent Quality of Life (ADDQoL).

In order to better describe the HRQoL of elderly diabetic patients in Slovenia, and following the recommendations from the Patient Reported Outcome Measurement Group (Patient reported outcome measures group 2009), both, generic (EQ-5D) and disease specific (ADDQoL) instruments were administered in this study.

In clinical, economic, and population health studies the EQ-5D can be applied to measure health status, while disease specific questionnaires are more sensitive in identifying disease-related changes in HRQoL (Patient reported outcome measures group 2009). The Slovenian value set for EQ-5D was calculated previously (Prevolnik-Rupel 2007; Prevolnik-Rupel and Ogorevc 2012), and the instrument is now being used in numerous interventions as the patient reported outcome measure. The ADDQoL is a valid and reliable diabetes specific HRQoL instrument, which is individualized, meaning that it allows for the patients to indicate which aspects of life apply to them by using the “not applicable” (N/A) options (Bradley et al. 1999).

The EQ-5D is a simple, generic, quality of life (QoL) instrument, intended as a measure which can be used for patients receiving treatment for many different conditions (EuroQol Group 1990; Kind 1996; Prevolnik-Rupel and Rebolj 2000; Szende et al. 2007).

For economic studies of the cost-utility variety a key feature of the EQ-5D is fully used, which is that peoples’ health states can be transformed to single numbers representing utilities. Nevertheless, there are many situations where simply reporting respondent information on the 5 dimensions might offer significant information. In this case the role of the EQ-5D is mainly to function as a generic HRQoL instrument. Furthermore, it is important to recognize that the EQ-5D has been specially designed to complement other HRQoL instruments (Krabbe and Weijnen 2003; Kind et al. 2005). Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D was originally designed to complement other instruments but is now increasingly used as a ‘stand alone’ measure (Kind et al. 2005; Szende et al. 2007). The EQ-5D is used in different
fields of research and can therefore reflect different methods of analysis, application, and presentation. According to the EuroQol Group (EuroQol Group 1990; Kind 1996), the particular interest of a researcher may determine whether 1 or more of the 3 parts (descriptive system, Visual Analogue Scale (VAS), and index) of the EQ-5D will be applied. EQ-5D outcomes are presented for each of these different research strategies. It is cognitively simple, taking only a few minutes to complete, and designed for self-completion by respondents and is suited for use in postal surveys, in clinics, and face-to-face interviews (Kind 1996; Kind et al. 2005). The instructions to respondents are included in the questionnaire (Rabin and De Charro 2001).

Scores for the EQ-5D are generated from the ability of the individual to function in five dimensions, which are Mobility, Pain/discomfort, Self-care, Anxiety/depression, Usual activities (work, study, housework, leisure activities). Each of the five dimensions used has three levels: no problem, some problems and extreme problems, i.e. making a total of 243 (3^5) possible health states, to which »unconscious« and »dead« are added to make 245 in total (Kind 1996; Rabin and De Charro 2001; Drummond et al. 2005).

While the descriptive system can be used as a health profile or converted into an index score representing a von Neumann-Morgenstern utility value for current health, VAS provides a direct valuation of the respondent's current state of health (Rabin and De Charro 2001). The level of problem reported on each of the EQ-5D dimensions determines a unique health state. Although EQ-5D has the advantage of being simple and easy to fill, the categories for responses are very broad (Prevolnik-Rupel 2007). Namely patients scoring in lowest range would be too ill to respond to questions 1–3, and there is too little differentiation at upper end (e.g. diabetes patients with problems could appear very healthy). Especially in diabetes problems with wording of second question might appear, as ‘self-care’ in diabetes is much more complex than the ability to wash and dress. Self-management of the condition was considered to be more important. In addition, the VAS scale does not add any additional information (Patient reported outcome measures group 2009). The scores serve as quality weights for calculating quality-adjusted life-years (QALYs). Health states are converted into a weighted health state index by applying scores from the EQ-5D preference weights elicited from general population samples. These weights lie on a scale on which full health has a value of 1 and dead a value of 0. QALYs consider both quantity and quality of life in a single metric, which is calculated as the arithmetic product of life expectancy and the QOL of the remaining life-years. One year of perfect health is
worth 1.0 QALY, one year of life in less than perfect health is worth less than 1.0 QALY, and dead is worth 0.0 QALY. QALYs are usually incorporated into decision analysis and cost-effectiveness (cost-utility) analyses of healthcare interventions at the policy level (Khanna and Tsevat 2007).

As shown above, EQ-5D may lack sensitivity to important differences in health status that are important for particular diseases. Therefore disease-specific questionnaires have an important role in gathering quantitative data. Disease-specific instruments focus on the issues most relevant to patients’ health concerns, having the detail to detect small, though clinically important changes in health status. They are thus not suited for a comparison of treatment results across various diseases (Drummond et al. 2005). Their main purpose is to assist in clinical decision-making, though they are also usually sensitive in measuring the results of specific treatments.

The Audit of Diabetes Dependent Quality of Life (ADDQoL) is an individualized instrument designed to measure an individual’s perceptions of the impact of diabetes on their quality of life (Bradley et al. 1999; Bradley and Speight 2002; Wee et al. 2006).

The questionnaire comprises 19 items where the respondent is invited to indicate, firstly, the effect of diabetes on a particular aspect of life and, secondly, how important this aspect of life is to overall quality of life. For the purpose of quality of data, ADDQoL was linguistically validated for the Slovenian language and was sent out simultaneously to the same population as EQ-5D.

The structure of ADDQoL is standardized in all languages and it begins with two global questions (table 8). The aim of the first question ‘In general, my present quality of life is’, is to provide a possible single-item indicator of QoL by assessing the participants’ present global QoL. On the other hand, the second global question, ‘If I did not have diabetes, my quality of life would be’, is a diabetes-specific item that aims to assess the diabetes-dependent global QoL (Bradley et al. 1999; Bradley and Speight 2002; Speight et al. 2003; Soon et al. 2010).

The two global questions are followed by 19 domain-specific items, which ask the participants to rate how particular aspects of their lives would be if they did not have diabetes. For each of these items, participants provide the impact (range -3 [greatest negative impact] through 0 [no impact] to +1 [positive impact]) and importance (range 0 [not at all important] to 3 [very important]) scores. The products of these two ratings for each domain are summed and then
divided by the number of applicable domains to produce the average weighted impact (AWI) score (Soon et al. 2010; Kong et al. 2011; Zhang et al. 2012b).

For five of the items, participants may select the ‘NA’ option if the item is not applicable to them. The scores of these items are set to ‘missing’ in computing the AWI scores. However, the scores are set to zero for the purpose of factor analysis so as to maximize data points. A more negative AWI score reflects a greater negative impact of DM on a participant’s QOL.

Table 8. Main questions of ADDQoL.

<table>
<thead>
<tr>
<th>Questions (English/Slovene)</th>
<th>Answers (English/Slovene)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global questions</strong></td>
<td></td>
</tr>
<tr>
<td>Present quality of life/Trenutna kakovost življenja</td>
<td>excellent – very good – good – neither good nor bad – bad – very bad – extremely bad</td>
</tr>
<tr>
<td>In general, my present quality of life is/</td>
<td></td>
</tr>
<tr>
<td>Kakovost mojega življenja je trenutno:</td>
<td>Odlična-zelo dobra-dobra-ne dobra, ne slaba-slaba-zelo slaba-izjemno slaba</td>
</tr>
<tr>
<td>Quality of life without diabetes/ Kakovost življenja brez sladkorne bolezni</td>
<td>very much better – much better – a little better the same – worse</td>
</tr>
<tr>
<td>If I did not have diabetes, my quality of life would be/</td>
<td></td>
</tr>
<tr>
<td>Če ne bi imel-a sladkorne bolezni, bi bila kakovost mojega življenja:</td>
<td>neprimerno boljša-precej boljša malo-boljša-enaka-slabša</td>
</tr>
<tr>
<td><strong>Disease specific questions</strong></td>
<td></td>
</tr>
<tr>
<td>For Part (a) Impact of diabetes on a certain domain of life</td>
<td></td>
</tr>
<tr>
<td>If I did not have diabetes, my (life domain) would be:</td>
<td></td>
</tr>
<tr>
<td>Če ne bi imel-a sladkorne bolezni, bi bila (domena)</td>
<td>Very much more – much more – a little more – the same – less neprimerno boljša- precej boljša- malo boljša-enaka-slabša</td>
</tr>
<tr>
<td>For Part (b): The importance of this domain of life is to quality of life</td>
<td></td>
</tr>
<tr>
<td>(Life domain) is for me:</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>(Domena) je zame:</td>
<td>zelo pomembna-pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
<tr>
<td>Questions (English/Slovene)</td>
<td>Answers (English/Slovene)</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td><strong>Domains in ADDQOL</strong></td>
<td></td>
</tr>
<tr>
<td>Family life (Družinsko življenje)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Friendship and social life (Prijateljstva in družabno življenje)</td>
<td>zelo pomembna -pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
<tr>
<td>Close personal relationship (Tesen osebni odnos)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Sex life (Spolno življenje)</td>
<td>zelo pomembna -pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
<tr>
<td>Physical appearance (Zunanji videz)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Physical health (Fizično zdravje)</td>
<td>zelo pomembna -pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
<tr>
<td>Work (employment) (Delovno/poklicno življenje)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Holiday (Počitnice)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Leisure activities (Dejavnosti v prostem času)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Journeys (Potovanja na krajše ali daljše razdalje)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Self-confidence (Samozavest)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Motivation (Motivacija)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>People’s reaction (Odziv ljudi)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Feelings about the future (Občutki glede prihodnosti)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Financial situation (Finančni položaj)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Dependence on others (Odvisnost od drugih)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Living condition (Življenjske razmere)</td>
<td>very important – important – somewhat important – not at all important</td>
</tr>
<tr>
<td>Freedom to eat (Svoboda, da jem, kakor želim)</td>
<td>zelo pomembna -pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
<tr>
<td>Freedom to drink (Svoboda, da pijem, kakor želim)</td>
<td>zelo pomembna -pomembna-še kar pomembna-sploh mi ni pomembna</td>
</tr>
</tbody>
</table>
4.2.3 Linguistic validation Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire

The Audit of Diabetes Dependent Quality of Life (ADDQoL) is a copyrighted questionnaire and for using the Slovenian version of ADDQoL, the questionnaire went through a linguistic validation process and obtained the licence by Prof. Clare Bradley, Health Psychology Research Ltd., University of London. According to the agreement, the translation of the ADDQoL into Slovene language, copies of the ADDQoL from a master copy for the purpose of carrying out the study were made. The linguistic validation formed a part of the thesis, and was performed according to the Handbook of Psychology and Diabetes (Bradley 2001) and Mapi Manual for Linguistic Validations of Patient Reported Outcome Instruments (Acquadro et al. 2004).

The Slovenian version of the ADDQoL was translated from the original English (UK) version using a standardized methodology of forward and back translation and in close collaboration with the instrument developers. Cognitive debriefing on a preliminary Slovenian version of the questionnaire was carried out among five native Slovene participants of diverse background with both DMT1 and DMT2 (aged 26–66 years; duration of DM= 2years to 4 years; education = primary to tertiary).

Of the 5 patients, there were 1 male and 1 female patient each with Type-1 diabetes; the other patients consisted of 2 female and 1 male DMT2 patients who were undergoing medication, diet control, and insulin injection respectively. Their consents to participate in the study were sought through an oral consent before the interview with the psychologist.

The first stage of the forward translation (FT) produced a preliminary Slovenian version from the original English ADDQoL. Two Slovene translators, both fluent in writing and speaking English, conducted the initial FT independently. After completion of the FT the project coordinator (doctoral student), together with the translators, produced a preliminary consensus version of the ADDQoL in Slovenian language (ADDQoL-SLO).

After the FT, two other bilingual translators were recruited to back translate the ADDQoL-SLO into English independently. Once the final reconciliation was completed, a backward translation report was compiled and sent to the developer. After revision and discussion with the developer, a preliminary ADDQoL-SLO was reconciled. This preliminary ADDQoL-SLO was subject to clinical and
psychological reviews, which were carried out separately, by a medical specialist in diabetology and a public health psychologist.

Only after consensus with the developer, cognitive debriefing was conducted. The conceptual equivalence, item equivalence and operational equivalence were discussed with participants during the interview with a clinical psychologist. Participants were asked about their view of health and QoL (conceptual equivalence), relevance of each item to themselves (item equivalence). In addition, they were asked about possible difficulties in understanding the items. Operational equivalence was assessed in two steps: first, participants were asked whether they were able to finish the self-administered ADDQoL; then, they were required to complete the questionnaire and discuss with interviewer about the appropriateness of the questionnaire format, instructions and mode of administration. The cognitive debriefing report was generated after the debriefing. The edited version of the ADDQoL-SLO was produced and subjected to reconciliation.

The original developer then did a review to ensure the authenticity of the translation. After the approval had been obtained, the final version of the Slovenian ADDQoL was produced. A process of the linguistic validation is shown in figure 11.

The phrases in the ADDQoL that were more difficult to translate into Slovene were ‘local or long distance journeys’ and ‘the way people in general react to me’. The challenge of achieving semantic equivalence with these phrases was overcome through many rounds of discussion between the translators and developers as well as cognitive debriefing among patients.
Fig. 11. Linguistic validation process of ADDQoL.
4.2.4 Systematic literature review

Search methods

Literature searches in NHS Economic Evaluation Database (NHS EED), Health Technology Assessment Database (HTA), Ovid MEDLINE, MEDLINE in Process and Other Non-Indexed Citations and EMBASE for economic evaluations and health technology assessment reports published from January 1, 2000 to August 26, 2010. The search strategies incorporated subject headings (for example MeSH terms in MEDLINE) and text words (in title and abstract) relating to DMT2 and multidisciplinary care. Search filters to identify economic evaluations were applied in the Ovid databases. All searches were repeated in October 2011. Reference lists of included studies were also examined for any additional relevant studies not identified through the searches. The flow chart of search process and results is presented in figure 12. The searches were performed twice in collaboration of the doctoral candidate and a research librarian. The first search was performed on August 26, 2010, and second on October 10, 2011. The abstracts were screened and the full text articles were read by the doctoral candidate. The reference lists of full text articles were checked for additional studies.

Fig. 12. Flow chart of search process and results.
Cost-effectiveness and cost-utility studies are recently gaining importance in health sciences. They are used to compare health outcomes and resource costs of various interventions (Polit and Beck 2007).

The aim of the systematic literature review was to assess the cost-effectiveness of the multidisciplinary teams. Inclusion and exclusion criteria were set for reviewing titles and abstracts. Inclusion criteria for study design were cost-effectiveness/cost-utility analyses (decision-analytic models) and health technology assessment (HTA) reports. Population criteria were adult patients with diabetes mellitus, and included outcomes were quality adjusted life years- QALY and Incremental cost-effectiveness ratio -ICER (see table 9), as well as life years (LY) gained. Further inclusion criteria were English language and adult (18 and over) patients with DMT2. Titles were excluded if the population was paediatric, or articles were concerned with pharmacologic interventions. Abstracts were rejected if they did not report costs, economic outcomes or HRQoL measurement of diabetes management.

### Table 9. Definitions of QALY and ICER.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality adjusted life years -QALY</td>
<td>QALY is a generic, widely used measure of health improvement, which captures both the quality and the quantity gains. QALY is used to guide health-care resource allocation decisions. It was originally developed as a measure of health effectiveness for cost-effectiveness analysis, a method intended to aid decision-makers charged with allocating scarce resources across competing health-care programs. One can then determine the cost per QALY and compare various interventions based on their relative costs for providing an added QALY (Drummond et al. 2005)</td>
</tr>
<tr>
<td>Incremental cost-effectiveness ratio - ICER</td>
<td>Is the ratio of the change in costs of an intervention (compared to the alternative) to the change in effects of the intervention (Drummond et al. 2005); <em>Incremental cost-effectiveness ratio (ICER) = (C1–C0) / (E1–E0)</em> Where C1 means the cost of the intervention; C0 is the cost of the control; E1 and E0 are the health effects, LY and QALYs, respectively.</td>
</tr>
</tbody>
</table>

### 4.3 Data collection

Data collection was organised with the help of diabetic out-patient clinics, health centres and general practitioners. A probability convenience sampling strategy was used, stratified by age and Slovenian regional diabetes prevalence.
The out-patient clinics were first contacted via telephone and their willingness to participate in the study was discussed. Participation in diabetes care of elderly people was used as the selection criterion of the study.

The inclusion criteria for participating the study was diabetes mellitus type 2 (DMT2) patients, aged 65 or older. These were approached in the out-patient clinics. Those who were willing to participate in the research received brief information in the health centres or by the general practitioners, or diabetic out-patient clinics, were structured questionnaires with detailed information.

Data gathering was twofold:
- In part 1 (Subproject 1) on the general diabetes knowledge test of 4 months (May- August 2011).
- In part 2 (Subprojects 2 and 3) the data were gathered in the period of 5 months (January- May 2012) for the PROMs.

In Subproject 1, 300 elderly diabetic patients were approached and agreed to participate in the study.

In Subproject 2 and Subproject 3, 500 elderly diabetic patients were approached and 391 agreed to participate in the study.

In addition to the doctoral candidate, medical students, who obtained thorough briefing on the study, handed out the questionnaires to the elderly diabetes mellitus type 2 patients in the out-patient clinics, waiting to see the doctor. Patients were asked to complete the questionnaires alone, only if needed, medical students were assisting the patients.

4.4 Data analysis

Sample data were presented by frequencies and percentages for categorical variables or by mean values and standard deviations (M±SD) for continuous variables. Statistical analysis was performed using IBM SPSS (Statistical Package for the Social Sciences) Statistics software, version 19.0.

In Subproject 1 (Paper 1), univariate analysis was carried out on demographic and study variables to obtain standard descriptive statistics (mean, standard deviation, frequency and percentage)(Polit and Beck 2007). The Shapiro-Wilk test was used for testing whether the data came from a normally distributed population (Field 2009). The level of general and specific knowledge about diabetes in rural and urban areas was compared using the non-parametric Mann-Whitney U test for independent samples. All significance tests were two-
tailed and a probability value of less than 0.05 was considered statistically significant. When multiple comparisons were performed the statistical significance level was adjusted by using the Šidák correction (Field 2009). An exploratory linear regression model was used to assess the influence of different variables on the questionnaire score (Field 2009).

In Subproject 2 (Paper 2) and Subproject 3 (Paper 3), the sample data were expressed as frequencies and percentages for categorical variables or by mean values and standard deviations (M±SD) for continuous variables. Binary logistic regression analysis was used to conduct influence of demographic and health characteristics of diabetes patients to their quality of life (Field 2009). The calculation included Wald, odds ratio (OR), 95% confidence interval (95% CI) and P value. Patients were divided into two groups by the ADDQoL score using quartiles; the first group in the lower quartile was considered as having lower quality of life. Such a cut-off strategy was previously applied in the literature (Trief et al. 2003; Chung et al. 2012).

In Subproject 4 (Paper 4), the abstracts of selected articles, which appeared relevant for this review, were retrieved and read through (Higgins and Green 2008). Based on the inclusion criteria, the eligible articles were selected. The main reasons for rejections were that the intervention was not multidisciplinary and the outcomes did not include Quality adjusted life years (QALY), or Incremental cost-effectiveness ratio (ICER), or life years (LY) gained.

To assess the quality of the studies, whether they described the methods, models and possible biases in a transparent way, the Evers’ checklist CHEC (Consensus on Health Economic Criteria)(Evers et al. 2005) was used. In the CHEC-list (figure 1), 19 points can be reached when aspects are addressed accurately in the article. The criteria are mainly about research question, right population definition and perspective from which the costs and effects are measured. Moreover, it measures if the relevant outcomes were measured, if a sensitivity analysis was performed etc. A high quality economic evaluation adequately addresses all 19 items of the CHEC-list.

Data were synthesized through a narrative review with tabulation of results from included studies. Studies were too diverse to be combined in a meta-analysis.
4.5 Ethical aspect

The project proposal was evaluated and approved by the Medical Ethical Commission in Slovenia in January 2011, Reference number 128/01/11, according to the Ministerial decree (Rules for Commission for Medical Ethics 1995).

The ethical principles addressed in the Declaration of Helsinki (World Medical Association 2008) were strictly followed. Protecting the privacy of research participants and the confidentiality of their personal information, as well as minimizing the impact of the study on their physical, mental and social integrity was guaranteed (World Medical Association 2008). All research involves some risks, and in the case of the present thesis the risk was assessed as minimal,
as no other risk than those ordinarily encountered in daily life occurred (Polit and Beck 2007). All the participants were informed about the nature of the study (information was given orally to all the participants), and what participation would entail for them (Puotiniemi and Kyngäs 2004). The participants were informed that the participation in the study was voluntary, and that the data will be used for research purposes. Anonymity was protected during the whole work, since no names were displayed and it is not possible to determine exact persons carrying out questionnaires. After informed consent was obtained, all participants were handed out the questionnaire. In case of need of assistance with filling in the questionnaire, patients obtained help from the medical students, who were specially educated to carry out the study process including obtaining oral consent and instructions related to the study instruments the instruments, and about the ethical considerations prior the launch of the study.

The data obtained were used only for the purposes of this research, and only the researchers were allowed access to the original collected material.

The permission to collect data was obtained from the heads of the respective out-patient clinics.

Permission to use the instruments was obtained in December 2010 by Michigan Diabetes Research and Training Center funded by DK020572 from the National Institute of Diabetes and Digestive and Kidney Diseases, and in January 2012 the licence was obtained by Prof. Clare Bradley, Health Psychology Research Ltd., University of London.

The doctoral candidate honestly reports data, results and methods.
5 Results

The results are reported according to the three phases of the study. The first phase describes the general diabetes knowledge of DMT2 elderly patients (Paper1). The second phase describes the results of PROM (Paper 2, 3). And the third section describes the evidence behind the cost-effectiveness of multidisciplinary teams (Paper 4).

5.1 General diabetes knowledge of DMT2 elderly patients

The aim of Subproject 1 was to evaluate the level of general knowledge and overall perceptions of diabetes mellitus type 2 among elderly diabetic patients in North-East Slovenia. Diabetes knowledge was used as an illustrative example to explore its potential impact on healthcare utilization.

The general diabetes knowledge portion consists of questions related to: (1) diet, (2) HbA1c, (3) hypoglycemia management, (4) activity, (5) effect of illness and infection on blood sugar levels, (6) foot care.

After obtaining the returned questionnaires (225), and elimination of the questionnaires where the subjects did not meet the eligibility criteria, 179 subjects were included in data analysis. Of those 85 lived in urban areas and 94 in rural areas. Of the included participants, not one single responded correctly to all 14 questions. The average score achieved by men was 8.8±1.9 and 7.6±2.5 by women. The most important predictor for better results level was education, while there was no significant difference between the elderly people living in urban and rural areas (figure 14). The detailed results are presented in (Paper1).
Fig. 14. Box plot of diabetes knowledge distribution between patients living in urban and rural areas.

An exploratory linear regression model following the backward stepwise method was used to assess the influence of different variables on the questionnaire score. No previous research on diabetes knowledge was conducted in Slovenia, thus the meaningful variables were chosen from the literature (Fitzgerald et al. 1998). The initial variables included in the model were the: age, education, place of living, sex, duration of illness and medicines taken per day, and the final model consisted of the following predictors: age, education and medicines per day. Table 10 shows the initial and final variables included in the model. Detailed model coefficients in the process are presented in Paper 1.
Table 10. Model coefficients.

<table>
<thead>
<tr>
<th>Steps</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>8.60</td>
<td>2.43</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.05</td>
<td>0.03</td>
<td>-0.14</td>
</tr>
<tr>
<td>Education</td>
<td>0.93</td>
<td>0.23</td>
<td>0.32**</td>
</tr>
<tr>
<td>Place of living</td>
<td>-0.33</td>
<td>0.34</td>
<td>-0.07</td>
</tr>
<tr>
<td>Sex</td>
<td>0.49</td>
<td>0.34</td>
<td>0.11</td>
</tr>
<tr>
<td>Duration of illness</td>
<td>-0.03</td>
<td>0.22</td>
<td>-0.01</td>
</tr>
<tr>
<td>Medicines per day</td>
<td>0.31</td>
<td>0.14</td>
<td>0.15*</td>
</tr>
<tr>
<td>Step 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>8.60</td>
<td>2.43</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.05</td>
<td>0.03</td>
<td>-0.15*</td>
</tr>
<tr>
<td>Education</td>
<td>1.07</td>
<td>0.21</td>
<td>0.37**</td>
</tr>
<tr>
<td>Medicines per day</td>
<td>0.31</td>
<td>0.14</td>
<td>0.15*</td>
</tr>
</tbody>
</table>

R²=0.20, *p<0.05, **p<0.01

In the final model, three predictor variables make a statistically significant contribution to the accuracy of prediction. The most important of the three was the level of education, while the contribution of age and medicines taken per day was roughly equal. From this, it can be concluded that the increasing age reflects negatively on the diabetes knowledge while higher levels of education and the number of medicines taken per day result in better scores.

5.2 Audit of Diabetes Dependent Quality of Life of elderly diabetic patients in Slovenia

The aim of Subproject 2 was to measure diabetes dependent quality of life in the elderly Slovenian diabetes mellitus type 2 (DMT2) patients.

In this subproject, 500 elderly diabetic patients were approached, and 391 returned the questionnaires. After exclusion of non-eligible respondents, a total of 285 were included in the analysis, which represents 57 percent response rate.

The participants’ age ranged from 65 to 84 year, with a mean of 70.0±4.9 years. Among the 285 respondents, less than half were females (135 cases, 47.4%), the majority was married (67.0%), and owned an own house (60.0%). The findings of the present study highlight the impact of DMT2 on health related quality of life. There was no significant difference between the elderly people living in urban and rural areas. 213 (74.4%) patients had an ADDQoL score at -3
or higher, and 72 (25.3%) of the patients reported an ADDQoL score below -3, showing lower quality of life. Patients with no associated health problems, such as heart attack, showed higher quality of life (OR 2.47, 95%CI 1.04–5.85). Heart attack episode was reported by 39 (13.7%) of the patients. Eleven patients report no impact of DMT2 on their quality of life at all, while in the remaining respondents, particular reference is put to the effects on ‘freedom to eat’, ‘dependency on others’ and ‘family life’. 114 (40.0 %) of patients were of the opinion to have their disease under control, which decreased the likelihood of a lower quality of life (OR 0.36, 95%CI 0.18–0.69). (Paper 2)

Table 11 presents the percentage of diabetes mellitus type 2 patients with problems or severe problems in the components of the EQ-5D, compared with the general population from the previous research (Rupel and Rebolj 2000). The EQ-5D questionnaire shows that diabetic patients report lower values in mobility; however in dimensions personal care, daily activities, and pain, they report fewer problems than the general population. The results basically show that they have good diabetic health conditions and their assessment, does not lag behind the general population.

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>DMT2 patients</th>
<th>General population</th>
<th>X^2</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Some Problems</td>
<td>% Severe Problems</td>
<td>% Some Problems</td>
<td>% Severe Problems</td>
</tr>
<tr>
<td>Mobility</td>
<td>37.1</td>
<td>0.3</td>
<td>30.7</td>
<td>1.0</td>
</tr>
<tr>
<td>Self care</td>
<td>7.6</td>
<td>0.8</td>
<td>15.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Usual activities</td>
<td>23.4</td>
<td>1.6</td>
<td>33.7</td>
<td>2.2</td>
</tr>
<tr>
<td>Pain/discomfort</td>
<td>39.5</td>
<td>4.2</td>
<td>47.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Anxiety/ depression</td>
<td>34.2</td>
<td>2.9</td>
<td>37.2</td>
<td>2.3</td>
</tr>
</tbody>
</table>

5.3 Reliability and validity of Patient reported outcome measures (PROMs) in DMT2 elderly patients

The aim of Subproject 3 was to evaluate the reliability and validity of the Slovenian Audit of Diabetes Dependent Quality of Life (ADDQoL) version among elderly diabetic population. The ADDQoL (Bradley et al. 1999; Speight et al. 2003) was compared against a generic instrument, the European Quality of Life-5 dimensions (EQ-5D) (Kind 1996; Rabin and De Charro 2001; Kind et al. 2005).
A possible response burden on study participants could be the length of the ADDQoL. Results indicate that none of responses had complete data, which would enable the calculation of scores on all domains, and the highest missing value (231, 59.1%) was in the domain ‘work life’. Analysis of item response patterns showed that four domains (‘work life’, ‘sex life’, ‘holiday’ and ‘personal relationship’) accounted for a large majority of the incomplete data. However, these items were almost entirely identified as Not Applicable. The two domains with the most missing items (‘work life’ and ‘sex life’) were omitted from the analysis. The lowest mean weighted impact score, meaning the least concern, was shown in ‘peoples’ reaction’ domain (-0.8, SD 1.6) and the highest weighted impact score, meaning the biggest concern, was in the ‘freedom to eat’ domain (-3.2, SD 2.9).

Cronbach’s alpha is a widely used measure of internal consistency, and it indicates how much the items on a scale are measuring the same underlying dimension (Polit and Beck 2007). The overall Cronbach's alpha for the 19-item ADDQoL was 0.93, indicating a very high level of internal consistency reliability, and there was no improvement in alpha value if any domains were deleted. Corrected item to total correlation coefficients ranged between 0.19 and 0.80. The only item, which did not meet the correction value of over 0.30, was ‘freedom to drink’ domain. The strongest correlation coefficient (0.79) was between self-confidence and motivation. Moderate inter-items correlation (0.30<r<0.70) coefficients were conducted in 80.9 percent of cases.

The Cronbach's alpha for the EQ-5D instrument was 0.73, and there was no improvement in alpha value if any items were deleted. Corrected item to total correlation coefficients ranged between 0.39 and 0.53, and the mean inter-item correlation coefficients ranged from 0.29 to 0.38, the lowest was 0.25 (usual activities vs. anxiety/depression). The strongest correlation coefficient was 0.58 between self-care and usual activities. Seventy percent of inter-items correlations were between 0.30 and 0.70 (moderate correlation).

Construct validity was examined by factor analysis. The forced one-factor solution using principal axis factoring analysis was applied to examine whether instrument items load to a single factor. For EQ-5D all items loaded to same one-factor solution, explaining 49.5 percent of total variance. For ADDQoL all items but ‘freedom to drink’ loaded to a one-factor solution. The forced one-factor solution explained 48.8 percent of total variance.

Calculated correlation between ADDQoL and EQ-5D was week therefore the use of specific patient reported outcome instruments like ADDQoL is
recommended, EQ-5D seems too generic to describe limitation of diabetes mellitus type 2 patients in more detail. (Paper 3)

5.4 Cost-effectiveness of multidisciplinary teams in DMT2 care

The aim of Subproject 4 was to critically appraise current evidence of analytic decision models and to summarize cost-effective studies of multidisciplinary teams in delivery of diabetes care. Patients with chronic conditions such as diabetes consume a substantial share of the healthcare resources, and there is a need of reorganisation to improve effectiveness and efficiency of care. In Slovenia, the Model Practices for diabetes care have been introduced in 2011, and although they offer great promise, it has not yet been demonstrated that they are able to reduce cost and improve care. As patient reported outcomes can be used to construct a quality adjusted life year (QALY), which is used for the cost-effectiveness study, literature was reviewed to find evidence of cost-effectiveness of multidisciplinary teams in diabetes care.

Four cost-effectiveness decision analytic models were included in the review: (Gilmer et al. 2007; Huang et al. 2007; O'Reilly et al. 2007; McRae et al. 2008). Of those, one study type was Cost utility analysis (Gilmer et al. 2007), and the rest were Cost effectiveness analysis (Huang et al. 2007; O'Reilly et al. 2007; McRae et al. 2008).

The population in included studies was general adult population with diabetes mellitus type 2. The baseline characteristics of the population are shown in table 12. The mean age reported in the studies was from 47.1 to 62.3 years, and the percentage of women ranged from 49 percent to 67 percent. All but one study reported the average duration of diabetes, which was at shortest 0.1 years and 9.2 years the longest. Mean HbA1c level varied from 6.9 to 9.4 and mean blood pressure measured was from 122.6 to 138.6 mmHg.
Table 12. Baseline characteristics of the population.

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.4</td>
<td>62.3</td>
<td>54.5</td>
<td>Uninsured: 47.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMS:51.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medi-Cal:51.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Commercial:55.2</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>49.4</td>
<td>51.3</td>
<td>67</td>
<td>Uninsured: 64</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMS:59</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medi-Cal: 68</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Commercial:49</td>
</tr>
<tr>
<td>Mean duration of diabetes</td>
<td>9.17</td>
<td>0.1</td>
<td>Not Reported</td>
<td>Uninsured: 5.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMS:6.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medi-Cal:8.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Commercial:6.9</td>
</tr>
<tr>
<td>Mean A1c</td>
<td>8.14</td>
<td>6.9</td>
<td>8.53</td>
<td>Uninsured: 9.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMS:8.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medi-Cal:8.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Commercial:7.8</td>
</tr>
<tr>
<td>Mean systolic blood pressure (mmHg)</td>
<td>138.7</td>
<td>135.1</td>
<td>133</td>
<td>Uninsured: 123.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CMS:128.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medi-Cal:126.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Commercial:122.8</td>
</tr>
</tbody>
</table>

The quality of the studies, according the CHEC-list, was acceptable, obtaining on average 12.5 points. All of the models performed sensitivity analysis. The highest ICER/QALY was $69,587 (€50,280), and the highest life years’ gain was 1.1. Most studies took into account only direct medical costs (Gilmer et al. 2007; Huang et al. 2007; O'Reilly et al. 2007; McRae et al. 2008). However, the costs are pictured in various ways. While one study estimates only the program costs under the societal perspective (Huang et al. 2007), another (Gilmer et al. 2007) gives mean direct lifetime costs, from the payer perspective.

Multidisciplinary teams seem a promising option to deliver treatment for diabetic patients and can be considered as a way of diabetes care management in Slovenia. However, the economic information in the literature is insufficient for policy decisions. The number of studies on cost-effectiveness of multidisciplinary teams is still limited (Paper 4).
5.5 Summary of the results

The main results show that the place of living (rural/urban area) does not have an impact on diabetes knowledge and the health related quality of life. Elderly diabetic patients show a low general knowledge of their disease (Paper 1). The most significant predictor for higher diabetes knowledge is the education level, while the increasing age is associated with lower diabetes knowledge. Polyparmacy, in this case, 5 medicines per day, is associated with better diabetes knowledge. The results of health related quality of life highlight the impact of diabetes mellitus type 2 (DMT2) on quality of life (QoL). Patients that responded that they have their diabetes under control showed a decreased likelihood of lower QoL, which addresses the importance of self-management of the disease. Only a few patients report no impact of DMT2 on their health related quality of life at all. However, in the rest, particular reference is put on the impact of ‘freedom to eat’, ‘dependency on others’ and ‘family life’. Furthermore, the results show that lower health related quality of life was significantly connected to presence of additional health problems (i.e. heart attack). Similar to the assessment of diabetes knowledge, living in rural environment was not significantly connected to lower quality of life (Paper 2). Lower quality of life is significantly connected to comorbidity (such as heart attack). With regard to reliability of the questionnaires, both, the Audit on Diabetes Dependent Quality of Life (ADDQoL) and EQ-5D showed good internal consistency. Moreover, both instruments proved to be valid and feasible for use among elderly DMT2 patients (Paper 3). The measurement of the general diabetes knowledge and health related quality of life among elderly DMT2 patients presents the baseline when introducing the new, multidisciplinary approach to chronic disease care in Slovenia. A straightforward decision whether multidisciplinary teams are cost effective cannot be made, as the studies varied in design and time horizon (4 to 40 years). Incremental cost effectiveness ratio (ICER) per quality adjusted life year (QALY) varied substantially, namely from $4,907 (€3,546) to $69,587 (€50,280). Thus, the evidence from the literature to draw health policy decisions is insufficient (Paper 4).
6 Discussion

This section begins with providing some general aspects, and discussing the validity and reliability of the research process and findings. It continues with discussion of the main findings and comparing them with the literature in accordance with research questions. Finally the implications and future research recommendations are presented.

6.1 General aspects

The aim of this thesis was to measure patient reported outcomes of diabetic patients above 65 years of age with nationally validated questionnaires. Health related quality of life and the general knowledge about diabetes among elderly diabetic patients were assessed to emphasize the importance of patient perspectives for better patient empowerment and self-management of diabetes mellitus type 2.

In addition to the above, and in line with the introduction of Model Practices for diabetes care, which will introduce the multidisciplinary approach, evidence was researched, if multidisciplinary teams in diabetes care are cost-effective elsewhere.

The literature identified no other published studies that measured patient reported outcomes among elderly diabetes mellitus type 2 patients in Slovenia. Thus, this was the first study in Slovenia to measure health related quality of life (HRQoL) and diabetes knowledge among elderly patients in Slovenia, and it provides a baseline for further research projects and evaluation of the current development of the diabetes care in Slovenia. The patient reported outcomes contribute the patient perspective to the delivery of care. They give insight and can be used to improve care processes; establish productive interactions between the multidisciplinary teams, patients, and their families. Patient reported outcomes, if collected and assessed continuously, can be reliable tools for shared decision making with patients at different levels of health literacy.

Similarly, the insufficient evidence of the cost effectiveness of multidisciplinary teams can trigger the use of the collected patient reported outcomes to conduct a cost effectiveness study of the diabetes model in Slovenia.
6.2 Validity and reliability of the study

The most important criteria in evaluation the quality of a study are validity and reliability (Polit and Beck 2007). Validity and reliability of measuring instruments are essential to detect true differences between study interventions (Polit and Beck 2009; Burns and Grove 2010). The guiding principles of conducting a valid study were the use of internationally valid and reliable questionnaires to provide a solid baseline for general diabetes knowledge and patient reported outcomes of elderly diabetic patients in Slovenia.

Reliability means the consistency of the measurement method (Burns and Grove 2010).

In Subproject 1, the Michigan Diabetes Knowledge test (MDKT) was applied, which has been recently used in other countries (Fitzgerald et al. 1998; Al-Adsani et al. 2009; Al-Qazaz et al. 2011; Saleem et al. 2011). Reliability of MDKT was examined by Cronbach’s alpha coefficient and corrected item to total correlation as suggested by Fitzgerald et al. (1998). Cronbach’s alpha for total sample was with 0.76 above the recommended threshold of 0.7. Corrected item to total correlation ranged between 0.31 and 0.43 and was consistent with the averaged behaviour of all items. Test reliabilities of MDKT instrument used in Subproject 1 are presented in table13.
Table 13. Test reliabilities of MDKT.

<table>
<thead>
<tr>
<th>Item</th>
<th>urban n=85 % correct</th>
<th>Corrected item-total correlation α*</th>
<th>rural n=94 % correct</th>
<th>Corrected item-total correlation α*</th>
<th>total n=179 % correct</th>
<th>Corrected item-total correlation α*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.73</td>
<td></td>
<td></td>
<td></td>
<td>0.77</td>
</tr>
<tr>
<td>Item 1</td>
<td>67.1</td>
<td>0.35</td>
<td>62.8</td>
<td>0.39</td>
<td>64.8</td>
<td>0.38</td>
</tr>
<tr>
<td>Item 2</td>
<td>62.4</td>
<td>0.38</td>
<td>70.2</td>
<td>0.42</td>
<td>66.5</td>
<td>0.43</td>
</tr>
<tr>
<td>Item 3</td>
<td>70.6</td>
<td>0.31</td>
<td>75.5</td>
<td>0.38</td>
<td>73.2</td>
<td>0.39</td>
</tr>
<tr>
<td>Item 4</td>
<td>23.5</td>
<td>0.39</td>
<td>7.4</td>
<td>0.40</td>
<td>15.1</td>
<td>0.41</td>
</tr>
<tr>
<td>Item 5</td>
<td>43.5</td>
<td>0.35</td>
<td>23.4</td>
<td>0.37</td>
<td>33.0</td>
<td>0.38</td>
</tr>
<tr>
<td>Item 6</td>
<td>69.4</td>
<td>0.34</td>
<td>74.5</td>
<td>0.38</td>
<td>72.1</td>
<td>0.40</td>
</tr>
<tr>
<td>Item 7</td>
<td>37.6</td>
<td>0.33</td>
<td>26.6</td>
<td>0.32</td>
<td>31.8</td>
<td>0.33</td>
</tr>
<tr>
<td>Item 8</td>
<td>12.9</td>
<td>0.34</td>
<td>7.4</td>
<td>0.31</td>
<td>10.1</td>
<td>0.31</td>
</tr>
<tr>
<td>Item 9</td>
<td>80.0</td>
<td>0.40</td>
<td>77.7</td>
<td>0.37</td>
<td>78.8</td>
<td>0.39</td>
</tr>
<tr>
<td>Item 10</td>
<td>55.3</td>
<td>0.42</td>
<td>58.5</td>
<td>0.35</td>
<td>57.0</td>
<td>0.43</td>
</tr>
<tr>
<td>Item 11</td>
<td>85.9</td>
<td>0.31</td>
<td>64.9</td>
<td>0.40</td>
<td>74.9</td>
<td>0.40</td>
</tr>
<tr>
<td>Item 12</td>
<td>84.7</td>
<td>0.33</td>
<td>79.8</td>
<td>0.35</td>
<td>82.1</td>
<td>0.39</td>
</tr>
<tr>
<td>Item 13</td>
<td>74.1</td>
<td>0.33</td>
<td>71.3</td>
<td>0.32</td>
<td>72.6</td>
<td>0.32</td>
</tr>
<tr>
<td>Item 14</td>
<td>71.8</td>
<td>0.43</td>
<td>68.1</td>
<td>0.42</td>
<td>69.8</td>
<td>0.43</td>
</tr>
</tbody>
</table>

*Cronbach's alpha coefficient

The Audit on Diabetes Dependent Quality of Life (ADDQoL) was developed in mid 1990s and there is robust evidence for its reliability, validity and responsiveness in English language (Garratt et al. 2002a; Wee et al. 2006; Soon et al. 2010; Ostini et al. 2011). The Slovenian version of ADDQoL resulted in high internal consistency (Cronbach's alpha of 0.93), which was consistent with international research. There was no improvement in alpha value if any items were deleted. Corrected item to total correlation coefficients ranged between 0.19 and 0.80 (Paper 3).

A generic instrument for health related quality of life assessment, the European Quality of Life – 5 Dimensions (EQ-5D) (Kind 1996; Rabin and De Charro 2001; Kind et al. 2005) was additionally applied. Cronbach's alpha of EQ-5D was 0.73, and there was no improvement in alpha value if any items were deleted. Corrected item to total correlation coefficients ranged between 0.39 and 0.53.

Validity refers to the degree to which inferences are accurate and well-founded as well as the degree to which an instrument measures what it is intended to measure (Polit and Beck 2009).
Content validity concerns the degree to which the items in an instrument adequately represent the completeness of the content of the concept being measured (Polit and Beck 2007; Polit and Beck 2009). Content validity was met by applying instruments that have been already used many times before and were also in process of validation before. Original instruments were translated to Slovene language using a standardized methodology of forward and back translation.

In next phase the construct validity of MDKT in Subproject 1 and the validity of ADDQoL and EQ-5D in the Subproject 3 were examined. Construct validity ensures that abstract concepts are measured adequately and logically, and relationships between variables are identified with the instrument based on theory, and clear operational definitions. It includes the definition of variables in line with existing literature or theory and differentiates between respondents who possess the trait and those without the trait (Burns and Grove 2009). Construct validity of all applied instruments was examined by factor analysis as suggested in the literature (Pett et al. 2003; Salkind 2004)

Factor analysis procedure: Kaiser-Meyer-Olkin measure of sampling adequacy and Bartlett's Test of Sphericity indicated that all three questionnaires used in the thesis met the assumption criteria for the factor analysis.

Kaiser-Meyer-Olkin measure of sampling adequacy for EQ-5D was 0.73 and Bartlett's Test of Sphericity ($\chi^2=328.453$, df=10, $p<0.001$). In the case of ADDQoL, Kaiser-Meyer-Olkin measure was 0.91 and Bartlett's Test of Sphericity ($\chi^2=1378.622$, df=136, $p<0.001$), and for MDKT, Kaiser-Meyer-Olkin measure of sampling adequacy was 0.60 and Bartlett's Test of Sphericity ($\chi^2=251.244$, df=91, $p<0.001$).

The forced one-factor solution using principal factor axis factoring analysis was applied to examine whether instrument items load to a single factor. For EQ-5D all items loaded to same one-factor solution, explaining 49.5 percent of total variance. For ADDQoL all items but ‘freedom to drink’ loaded to a one-factor solution, item ‘freedom to drink’ loaded with a value of 0.188 into this factor. The forced one-factor solution explained 48.8 percent of total variance. For MDKT 12 out of 14 items loaded to a one-factor, two items had loadings below the threshold of 0.4; one-factor solutions explained 47.3 percent of total variance. Validity of instruments in general corresponded to international research cited in Papers 1 and 3, instrument structure was calculated according to predefined criteria with only few exceptions. A forced one-factor solutions explained about 50 percent of the observed variance which can be considered as an adequate result (McColl et
Structure validity testing results are presented in Table 14.

<table>
<thead>
<tr>
<th>Item</th>
<th>ADDQoL</th>
<th>EQ-5D</th>
<th>MDKT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>0.671</td>
<td>0.658</td>
<td>0.429</td>
</tr>
<tr>
<td>Item 2</td>
<td>0.545</td>
<td>0.581</td>
<td></td>
</tr>
<tr>
<td>Item 3</td>
<td>0.714</td>
<td>0.738</td>
<td>0.479</td>
</tr>
<tr>
<td>Item 4</td>
<td>0.738</td>
<td>0.672</td>
<td>0.235</td>
</tr>
<tr>
<td>Item 5</td>
<td>0.751</td>
<td>0.452</td>
<td>0.333</td>
</tr>
<tr>
<td>Item 6</td>
<td>0.734</td>
<td>0.477</td>
<td></td>
</tr>
<tr>
<td>Item 7</td>
<td>0.787</td>
<td>0.486</td>
<td></td>
</tr>
<tr>
<td>Item 8</td>
<td>0.722</td>
<td>0.464</td>
<td></td>
</tr>
<tr>
<td>Item 9</td>
<td>0.400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 10</td>
<td>0.752</td>
<td>0.401</td>
<td></td>
</tr>
<tr>
<td>Item 11</td>
<td>0.818</td>
<td>0.423</td>
<td></td>
</tr>
<tr>
<td>Item 12</td>
<td>0.822</td>
<td>0.474</td>
<td></td>
</tr>
<tr>
<td>Item 13</td>
<td>0.594</td>
<td>0.451</td>
<td></td>
</tr>
<tr>
<td>Item 14</td>
<td>0.730</td>
<td>0.677</td>
<td></td>
</tr>
<tr>
<td>Item 15</td>
<td>0.679</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 16</td>
<td>0.826</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 17</td>
<td>0.693</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 18</td>
<td>0.472</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 19</td>
<td>0.188</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Feasibility of the applied instruments was addressed by missing data calculation as suggested by Pitkänen and colleagues (Pitkänen et al. 2012). Missing data for EQ-5D items ranged from 0.8% to 1.5%, most for the anxiety/depression item, while for ADDQoL 59.1 percent were missing when patients were asked about their ‘work life’, and 36.8 percent were missing when asked about ‘sex life’. These two items were excluded from the analysis due to mainly retired population, which had lived for most of their lives in a culture where talking about sexuality was a cultural taboo. After the exclusion of these two items, missing data were recorded from 0.8 percent (‘freedom to drink’) to 27.4 percent (‘holidays’).

The MDKT instrument was applied to test knowledge of diabetes mellitus type 2 patients about the diabetes disease (Paper 1). Missing data in knowledge test instruments are primarily connected to lack of knowledge and inability to
provide correct answer to the question. In the present study no missing data in 14-item instrument was recorded among 179 participants.

The limitations of the thesis have been discussed in the original articles (1–4). The main limitation of the current study is the sampling issue. Slovenian diabetes care has no relevant international research and patient reported outcomes are not systematically assessed, thus the lack of patient perspectives is evident in the delivery of care.

The lack of a randomized sampling and use of a convenience sampling limit the ability to generalize the results. Due to patients’ willingness to participate in the study, a response bias might have occurred. A larger sample would provide more power to detect significant relationships between the study variables and differences between groups. Nevertheless, the findings of this study could be useful to compare patients reported outcomes to similar research in other countries.

Due to the limited resources, the Subproject 1 was a cross sectional study by convenience sampling in only one region of Slovenia. Hence the results of this study cannot be generalised for the whole country.

The Subprojects 2 and 3 give an overview of elderly diabetic patients’ self-perceived quality of life. The main strength of the ADDQoL is that it measures quality of life in various areas of people’s lives. This, however, can have a consequence that not all areas are applicable to all respondents. As a result, some respondents did not provide complete data for all ADDQoL domains, which may have introduced unintended biases into the analyses.

In the Subproject 4, the literature review conducted has its limitations. Firstly, some relevant studies might have been missed due to the search filters used. Secondly, the scientific articles were appraised by a single person; however after the second search all the abstracts were reviewed and checked for inclusion criteria again. When the outcome of the search is limited to economic outcomes only, a more detailed definition of those should be in place. As a consequence, there is a potential for improvement in the outcome as evidenced by variations of economic outcome achievement. Moreover, the definition of multidisciplinary care is very broad and in this systematic review, for the purpose of clarity we chose the definition that includes at least a nurse and a physician.
6.3 Discussion of results

In order to explore patient reported outcomes, such as diabetes knowledge and health related quality of life of the elderly diabetes mellitus type 2 (DMT2) patients in Slovenia, first diabetes knowledge was measured, afterwards the instrument Audit of Diabetes Dependent Quality of Life (ADDQoL) was validated and health related quality of life of elderly DMT2 patients was examined using EQ-5D and ADDQoL instruments. In addition, the results were analysed to understand the gaps and give recommendations for upgrading the Model Practices for diabetes care in Slovenia. In line with this recommendation, and to find the evidence whether multidisciplinary approach is cost-effective, a systematic literature review was conducted.

Conducted studies show that the place of living does not impact the patient reported outcomes in Slovenia. This was proven when showing no difference in health related quality of life between rural and urban areas, and gaps in diabetes knowledge of elderly DMT2 patients exist regardless the place of living. The study presents the health related quality of life as a potential outcome for evaluating the newly implemented Model Practices at the primary level in Slovenia. The patient reported outcomes measurement (PROM) has opened the question of further investigation of the diabetes care management in Slovenia. As seen from figure 15, in theory, improved PROMs can be achieved through the good collaboration between empowered patient and the multidisciplinary team.
To achieve improved patient outcomes (both, clinical and health related quality of life) productive interactions between patients and health professionals are needed. The productive interactions present an essential element of the Chronic Care model (Bodenheimer et al. 2002; Wagner et al. 2005). This means that chronic disease care gets done in a systematic, coordinated way by using clinical and behavioural evidence-based care, and patient needs are met (Wagner et al. 1999; Wagner et al. 2005; Brusamento et al. 2012; Knai et al. 2012; Nolte et al. 2012b). To achieve a productive interaction, educated, informed and activated patients need to be involved in the care together with the multidisciplinary team of health professionals (Wagner et al. 1999; Wagner et al. 2005; Watts et al. 2009; Watts et al. 2011). For the patients to become wise decision-makers, and self-managers of the disease, they need sufficient, timely and clear information regarding their illness. In addition to information, the knowledge and understanding, skills, and confidence, as well as motivation to change their lifestyle, are necessary for patients to manage their disease well. Continuous education on disease
management and prevention can help patients reach clinical targets and improved self-management goals (Watts et al. 2009; Watts et al. 2011).

A theoretical model of diabetes management to upgrade the Model practices is recommended and shown in figure 16. The key element of the model is the multidisciplinary team which provides the patient with the information package about the disease, prepares and evidence based diabetes management plan with preventive actions needed (such as body weight, exercise, diet, blood glucose). It also enables suitable diabetes education which enables the patients to take a more active role and be more competent managers of their health and healthcare. In addition to medication needed, the team ensures continuous screening for complications. Furthermore, in the model, modern support of self-management and monitoring to assist the patient is ensured. As health related quality of life represents an important factor in patients’ lives, and it serves as an element of quality and cost effectiveness of care, patient reported outcomes are regularly assessed.

Evidence from the literature about the cost effectiveness of multidisciplinary care was inconclusive (Paper 4), meaning that the policy makers might lack sufficient information for decision making. Hence, the collection of patient reported outcome data of diabetic patients in Slovenia should be promoted on a regular basis in the future. This way a national evaluation of the Model Practices could be carried out.
6.3.1 General knowledge about diabetes

The aim of Subproject 1 was to measure the general knowledge about diabetes mellitus type 2 among elderly diabetic patients. To obtain the situation in Slovenia, in one of the most diabetes prevalent regions (Buzeti and Gobec 2012), Drava region, the elderly diabetic population was surveyed regarding its level of knowledge of diabetes. The study found that the diabetes knowledge among
elderly diabetic patients is unsatisfactory, with no significant difference if patients are living in urban or rural areas.

Knowledge and awareness about the disease have evidently been one of the major factors for proper self-management of the disease (Heisler et al. 2002; Eckman et al. 2012). Especially in old age, where patients need to cope with multiple chronic diseases, the knowledge is crucial (Sinclair et al. 2000; Gary et al. 2003; Sinclair 2003; Ellis et al. 2004; Funnell et al. 2011). Diabetes education is an important cornerstone of diabetes care, and supports the philosophy of the chronic disease model (Funnell et al. 2009; Peyrot et al. 2009). Researchers on diabetes education programmes have adequately demonstrated increased participant knowledge and corresponding improvements in glycaemic control and improved physical functioning (Hänninen et al. 2001; Norris et al. 2002b; Ellis et al. 2004; Atak et al. 2008; Funnell et al. 2009). Self-management shows positive effects on health related quality of life in diabetes, and collaborative learning approach improves knowledge (Heinrich et al. 2010).

The present thesis shows gaps in knowledge of elderly patients regarding classic symptoms of diabetes, where two thirds of the subjects were unable to give the correct answer to the meaning of HbA1c. Long ago, researchers have found evidence (Turner et al. 1998) that good blood sugar control correlates with lower risk of developing major related health problems, such as cardiovascular diseases, kidney disease, eye disease, nerve damage, amputations and circulation problems. In order to reduce the burden of the chronic disease, and be empowered for self-care, the diabetes patients should receive continuous education on the disease management. When a patient is newly diagnosed of diabetes mellitus type 2, he/she receives a lot of information about the disease firstly from the physician, nurse, diabetes education classes, which are group sessions in Slovenia, as well as from pharmacists and other diabetic patients (Villanyi and Wong 2007). It is important that the patients understand the received information. Moreover, the type of knowledge they acquire is also important. Literature shows correlation between knowing of the HbA1c value and a better understanding of diabetes treatment (Heisler et al. 2005). However, in literature, this did not translate into the increased confidence and motivation necessity to improve their diabetes self-management.

The results of the study demonstrate that the place of living does not influence the level of general diabetes knowledge. This suggests that the accessibility to the healthcare services and diabetes educators does not differ a lot in North – East Slovenia. The results further showed the level of education being
the most important predictor of general knowledge about diabetes, which is in line with other research in the literature (Schillinger et al. 2002; Schillinger et al. 2004). It is shown that with increasing age, the diabetes knowledge decrease, while patients who are taking more medicines per day, will generally show higher knowledge of diabetes. As 58 percent of the respondents are taking more than 5 medicines per day, it is important that they obtain the knowledge and understanding of diabetes management to avoid the adverse events and complications due to polypharmacy. Villanyi and Wong (Villanyi and Wong 2007) showed in their study that despite high self-reported understanding of diabetes and its treatment, 24.5 percent of subjects made at least one error with regard to their medication treatment. Interventions like computerised decision support and multifaceted pharmaceutical care to improve appropriate polypharmacy show so far limited evidence in ensuring that elderly people are receiving the right medicines and reducing medication-related problems (Ham 2010; Patterson et al. 2012). Due to unsatisfactory diabetes knowledge of the elderly diabetic patients in Slovenia, concern about the involvement of patients in their self-management can arise. Thus efforts need to be focused on educational programmes for the elderly diabetic patients with strategies to assist them in managing their disease more effectively.

6.3.2 Patient reported outcomes

In Subprojects 2 and 3, I attempted to understand the meaning patient reported outcomes from the perspectives of the Slovene elderly diabetic population. Patient reported outcome measures (PROMs) provide validated evidence of health from the point of view of the patient, and thus offer great potential to improve the quality and results of health services. PROM data are important to health professionals as feedback on the care they have provided. There is good evidence that an individual’s own judgement about his or her health status has a high predictive value for outcome (Leplège and Hunt 1997; Devlin and Appleby 2010). PROMs are especially useful for describing the human costs associated with diabetes mellitus type 2 (DMT2) (Devlin and Appleby 2010; Vieta et al. 2011).

The impact of diabetes mellitus type 2 on health related quality of life of elderly diabetic patient in Slovenia is demonstrated in Paper 2. Interestingly, a few patients report no impact of DMT2 on their quality of life (QoL) at all. However, in the rest, not surprisingly ‘freedom to eat’ was most affected by DMT2, which is
indicating the strong influence of dietary restrictions on QoL and supports prior research (Akinci et al. 2008; Holmanová and Žiaková 2009; Kong et al. 2011). This item was followed by ‘dependency on others’, which demonstrates diabetic patients’ need to self-manage the disease. Similarly to previous research, the least affected domain was ‘people’s reaction’ (Holmanová and Žiaková 2009; Kong et al. 2011). The effect of specific socio-demographic and clinical factors was fairly modest, as was also shown elsewhere (World Health Organisation 1999; Trief et al. 2003; Collins et al. 2009; Chung et al. 2012). However, the study showed no connection with place of living and health related quality of life (HRQoL). This finding suggests that accessibility to chronic disease care provision and information does not depend on the place of living in Slovenia. This is in accordance with the European Health Interview Survey study – EHIS (National Institute of Public Health 2007), which suggests that the use of primary level care is relatively evenly spread across socioeconomic classes in Slovenia.

The results show that lower quality of life was significantly connected to co-existing medical conditions. Bearing in mind, that the results from the present study showed a lower quality of life of older diabetic patients with additional health problems, it is necessary to emphasize the preventive actions, and education in Model Practices to avoid further complications of diabetes. Evidence shows (Norris et al. 2002a; Chodosh et al. 2005; Peyrot et al. 2009; Khanna et al. 2012) higher quality of life when patients manage their disease well and have it under control. The study underlines the existing evidence, namely decreased the likelihood of lower quality if patients are of the opinion they have their disease under control was showed. Nevertheless, in Slovenia, only 40 percent of the participants thought they control their disease. These findings underscore not only the importance of preventing and treating complications of diabetes to prevent further deterioration in HRQoL among elderly diabetic patients (Zhang et al. 2012a), but also the necessity to emphasize patient empowerment and self-management in Slovenia. The findings, moreover, highlight the need to identify factors that may be modulated to improve HRQoL in these patients. Towards this end, a reliable and valid patient reported outcome instruments is Slovenia can contribute to measuring the health related quality of life.

As shown in the earlier review of PROM instruments (Patient reported outcome measures group 2009), numerous instruments have been used to assess health related quality of life in diabetes. The recommendations from the PROM Group (Patient reported outcome measures group 2009) are the use of European Quality of Life-5 Dimensions (EQ-5D) in combination with a diabetes specific
patient reported outcome measure (PROM), preferably the Audit of Diabetes Dependent Quality of Life (ADDQoL). Since no accessible disease specific PROM existed in Slovenia prior to this study, a linguistic validation of ADDQoL was conducted, and the generic (EQ-5D) and diabetes specific (ADDQoL) instruments were tested for reliability and validity among elderly diabetes mellitus type 2 patients (Paper 3). Both instruments are described in detail in the Materials and methods section. The ADDQOL exhibited good psychometric properties in elderly diabetic patients. One-factor scale structure was supported and internal consistency showed to be high (Cronbach’s alpha = 0.93). The construct validity of ADDQOL was also demonstrated. A low missing data to the EQ-5D might indicate that the participants found it to be more easy to use than ADDQoL. Nevertheless, 67 percent (n= 261) of 391 participants who agreed to participate in the study, were able to be retained, a number that is common for the comprehensive instruments. More details about missing data for EQ-5D and ADDQoL are presented in Paper 3.

Consistent with other studies of Patient reported outcome measures (PROMs) in the world (Costa et al. 2006; Wee et al. 2006; Akinci et al. 2008; Collins et al. 2009; Holmanová and Žiaková 2009; Soon et al. 2010; Kong et al. 2011; Ostini et al. 2011; Chung et al. 2012; Zhang et al. 2012b), this analysis showed that both instruments are reliable. Factor analysis, Cronbach’s alpha index showed satisfactory results in multiple aspects of the ADDQoL scale, implying that the scale was well translated and culturally adapted for Slovenian people and could be widely used in Slovenia. The main strength of the ADDQoL is that it measures quality of life in specific areas of people’s lives.

The structured and continuous care seems to be an important factor of good health related quality of life in people with diabetes mellitus type 2 (Levitt et al. 2010). Decreased likelihood of lower quality of life in diabetic patients suggests the importance of self-management, considering the necessity of continuous care. This is in line with previous research which showed, that health related quality of life was found to be associated with regular care, continuity of care, visits to a diabetes nurse, and satisfaction with diabetes education (Wändell 2005) and that diabetic patient who have had a permanent physician–patient relationship seemed to have better mental health and less pain and felt more healthy in themselves than those without it (Hänninen et al. 2001; Ose et al. 2009). Furthermore, implementation of the Chronic Care Model was significantly related to health related quality of life and it can reorient care delivery toward more proactive
behaviour change and improvements in patient health outcomes (Hung et al. 2008; Stock et al. 2008).

Diabetes affects a substantial number of people and contributes considerable to the healthcare spending in Slovenia. It is difficult to assess the ‘before and after treatment’ patient reported outcomes in diabetes care (Devlin and Appleby 2010), as the diabetes management is a complex process. Therefore the measurement of patient reported outcomes in the Model Practices delivering diabetes care, need to become a continuous process of recording trends in diabetic patients. By doing so, the patient perspectives can be included in the important aspects of diabetes care. Patient perspectives will be important for measuring and benchmarking the performance of Model Practices, and referrals from them to secondary care. Furthermore, they can enable healthcare professionals to monitor and improve their practices. Last but not least, due to increasingly higher prevalence and increasing economic burden of diabetes in Slovenia, PROMs can contribute to the more accurate assessment of the effectiveness of the Model Practices. It is namely important to assess the cost-effectiveness of diabetes care models to ensure the sustainability of healthcare and economic resources.

6.3.3 Cost-effectiveness of multidisciplinary teams in DMT2 care

Subproject 4 dealt with investigating the cost effectiveness of multidisciplinary teams in diabetes care. Limited financial and healthcare resources have created a demand for more efficient delivery of care. In the case of growing prevalence of chronic diseases like diabetes, which are posing a high economic burden of the health system in Slovenia, new methods of disease management that provide cost-effective resource spending are needed. In Slovenia, diabetes care is fully reimbursed by the Health Insurance Institute (HIIS). Therefore new programmes, such as the introduction of Model Practices, and interventions in healthcare provision are scrutinised and need to be evaluated for effectiveness and cost-effectiveness. Economic outcomes show a meaningful outcome, as to have an overview how the financial and also human resources are allocated. However, only direct costs do not show the full picture of the economic implications for the health system. In order to provide an economic argument for the implementation of the Model Practices in Slovenia, they need to be cost-effective.

Due to the lack of data in Slovenia, evidence of cost-effectiveness of multidisciplinary teams was searched in the literature. The results of the studies included in the literature review showed weak improvements in economic
outcomes when implementing multidisciplinary diabetes care. With regard to feasibility of the chosen economic outcomes it can be argued that due to the complexity of health systems across the world it is difficult to find “one size fits all” disease management program. Moreover, in contrast to clinical outcomes, quality adjusted life years (QALYs) depend on many variables and are more difficult to measure. Hence no strong evidence on cost-effectiveness of multidisciplinary teams in diabetes care exists in the literature. Nevertheless, the results indicate, that multidisciplinary care can improve the cost-effectiveness of diabetes care. Whenever a program is addressing long term chronic diseases, i.e. diabetes, it is necessary to use modelling approaches to estimate long term outcomes and costs. Therefore, a Slovenian cost-effectiveness study of the Model Practices will be needed. The patient reported outcomes collected as part of the thesis, can provide the baseline data when calculating the QALYs.
7 Conclusions

Diabetes mellitus type 2 is a massive public health problem and it has major implications on quality of life, healthcare utilization and societal productivity. Diabetes management is complex and effective management requires creation of care models that take account of this complexity and facilitate care providers to attain multiple treatment targets and empower patients to adhere to self-management.

In general, the results from the Subprojects performed for this thesis can contribute to the improved understanding of patient reported outcomes in diabetes mellitus type 2, which can be a measure in assessing diabetes care program in Slovenia. The main contributions of the studies are summarized as follows:

This was the first study to measure general diabetes knowledge of elderly diabetic patients in Slovenia. For an elderly diabetic patient, to become empowered and self manage the disease, first and foremost he/she needs to obtain the knowledge and understanding of the disease. The study shows gaps in diabetes knowledge and thus emphasises the importance of continuous education of elderly diabetic patients.

Secondly, a pioneering example of measuring patient reported outcomes in elderly diabetic patients in Slovenia, using a validated and reliable instrument (ADDQoL) was provided. A study to evaluate the relationships between diabetes mellitus type 2 and other co-existing chronic medical conditions on quality of life was performed. The study contributes to the knowledge of patient reported outcomes in elderly diabetic patients in Slovenia by using the diabetes-specific health related quality of life instrument, which is more sensitive than generic instruments detecting changes in health related quality of life (Matza et al. 2004). Information on the health related quality of life of elderly diabetic patients is important to Slovenian policy makers and health professionals to identify and implement appropriate interventions for achieving better management of diabetes and ultimately improving the quality of life of diabetic patients.

Thirdly, a systematic way of finding evidence for understanding the cost-effectiveness of multidisciplinary teams was applied. Even though the evidence is inconclusive, through the regular collection and analysis of patient reported outcomes in the future, a national evaluation of the Model Practices can be carried out.

Efficient and rational diabetes care needs to be encouraged in Slovenia. This can be achieved via mechanisms that involve multidisciplinary teams and patient
empowerment, where the patients will co-manage their care. Patient reported outcomes serve as important factors in organisation of diabetes care, since the subjective valuation of health state dimensions represents a factor that has a strong impact on quality of life. Namely, it is used to determine the orientation and allocation of financial resources in healthcare system. The results show no difference with regard to patients living in urban or rural areas, implying an equal accessibility to the health care organisations. Elderly patients need to be continuously educated about their disease, as their knowledge about the disease showed to be suboptimal. Patient reported outcomes, which have been measured in this thesis, can serve as a baseline for evaluation of the Model Practices, where the patient reported outcomes of diabetic patients shall be collected and analysed continuously as one of the performance indicators for this kind of model, in addition to the clinical outcomes. This research has demonstrated the necessity to improve disease knowledge of the elderly diabetic patients, and increase the diabetes education in the Model Practices, so that patients can become empowered and act as a partner in diabetes care. Furthermore, the routinely collected patient reported outcomes can contribute to assessing and benchmarking the performance of Model Practices in Slovenia. Likewise, they can enable healthcare professionals to monitor and improve their practices. Last but not least, they can present the basis for assessing cost-effectiveness of the multidisciplinary teams in the Model Practices.

In order to further improve the delivery of diabetes care in Slovenia, it is recommended to incorporate elements of Chronic Care Model in the organisation of the Model Practices. Emphasis needs to be put on how we can encourage both patients and health professionals to engage in productive interactions in daily diabetes care practice, which can improve clinical and patient reported outcomes.
8 Recommendation for future research

The thesis raises the importance of structured diabetes care, where the patient reported outcomes should be measured continuously. The current results of the thesis can represent a baseline for the preliminary evaluation of the Model Practices in Slovenia, and can set the basis for future development of the Model Practices where the diabetic patient should be included in the multidisciplinary care team as an equal partner. Furthermore, the thesis stresses the importance and need of consistent and credible information and education for the patients (and their loved ones) about the disease. Since diabetes mellitus type 2 often requires the patients to restate their own system of values, only knowable patients will have the understanding and motivation to build a sufficient level self-management, which (in combination with the Chronic Care Model elements) can increase the health related quality of life. Thus, research on effectiveness of education methods for diabetic patients can be conducted in the future.

The doctoral thesis can open up new interesting research opportunities. For example, the current Audit on Diabetes Dependent Quality of Life can be extended to the wider diabetes mellitus population to compare the influences comorbidity on health related quality of life measured using generic, disease-specific and individualized instruments.

It would be interesting to further research the correlation between the knowledge of disease and the health related quality of life on the Slovenian diabetic population, which was impossible in this study due to different study populations in the Subprojects.

Furthermore, the combination of generic and disease specific questionnaire can serve as the tool to assess the cost-effectiveness of the newly implemented Model Practices, which will be needed in light of the allocation of the resources.

Additional research opportunities arise in conducting a benchmarking analysis of the Model Practices, using the patient reported outcome measures.
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**Articles included in the Systematic literature review (Paper 4)**
Appendix 1- Michigan Diabetes Knowledge test (MDTK)

Spoštovani!

Želeli bi vam postaviti nekaj vprašanj glede vašega vedenja o sladkorni bolezni.
Raziskava se odvija v okviru doktorskega študija.
Zagotavljamo vam, da bomo zagotovili vašo anonimnost. Posredovani podatki bodo uporabljeni zgolj v raziskovalne namene.

Prosimo, da obkrožite črko pred odgovorom.
Izpolnitev vprašalnika vam bo vzela okvirno deset minut časa.

Zahvaljujem za vaš dragocen prispevek!

Mag. Eva Turk, Izštitut za varovanje zdravlja

Spoštovani podatki:

Spoj (obkrožite)

a. Ženski
b. Moški

Starost (vpisište)____

Izobrazba
a. Osnovnošolska
b. Srednješolska
c. Končana višja/visoka šola
d. Fakultetna
e. Magisterij/doktorat

Kraj bivanja

a. Mesto
b. Podçeželje

Zaposlitveni status

a. Študent/ka
b. Zaposlen/a
c. Nezaposlen/a
d. Upokojenec/ka

Trajanje sladkorne bolezni

a. 2-5 let
b. 6-10 let
c. več kot 10 let

Število zdravil, ki jih užijete dnevno:

a. 1
b. 2
c. 3

d. 4

e. 5 in več

GLAVNI VPRAŠALNIK

1. Prehrana, primerna za bolnike s s slaldorno boleznijo pomeni:
   a. tako se prehranja večina ljudi
   b. zdrava prehrana, kakor je primerna za večino ljudi
   c. vsebuje več ogljikovih hidratov, kakor bi bilo primerno za večino ljudi
   d. vsebuje več beljakovin, kakor bi bilo primerno za večino ljudi

2. Kaj od naštetega vsebuje največji delež ogljikovih hidratov?
   a. Pečen piščanec
   b. Švicarski sir
   c. Pečen krompir
   d. Maslo

3. Kaj od naštetega vsebuje največ maščob?
   a. Posneto mleko
   b. Pomarančeni sok
   c. Koruza
d. Med

4. Kaj od naštetoa je hrana, ki jo lahko jeste brez omejitev?
   a. Vsa nesladkana živila
   b. Vsa dietetična živila
   c. Vsako živilo, pri katerem na etiketi piše "brez sladkorja"
   d. Vsa živila, ki vsebujejo manj kot 20 kalorij na obrok

5. Glikiran hemoglobin (HbA1c) je merilo vaše povprečne ravni glukoze v kri v preteklem/preteklih:
   a. dnevu
   b. tednu
   c. 6-10 tednih
   d. 6 mesecih

6. Kateri je najboljši način testiranja glukoze v kri?
   a. Testiranje urina
   b. Testiranje kri
c. Oba sta enako dobra

7. Kako vpliva nesladkan sadni sok na raven glukoze v krvii?
   a. jo znižuje
   b. jo dviguje
   c. Nima učinku

8. Kaj od naštetega se NE SME uporabljati za dvig prenizke ravni glukoze v krvii?
   a. 3 trdi bonboni
   b. 1 / 2 kozarca pomarančnega soka
   c. 1 kozarec brezalkoholne osvežilne pijače
   d. 1 skodelica posnetega mleka

9. Za osebo, ki ima dober nadzor nad krvnim sladkorjem, kakšen učinek ima telesna vadba na raven glukoze v krvii?
   a. jo znižuje
   b. jo zvišuje
   c. Nima učinku
10. Okužba lahko povzroči:
   a. povečanje glukoze v krv!
   b. znižanje glukoze v krv!
   c. ne povzroča spremembe glukoze v krv!

11. Najboljši način skrbi za svoje noge je:
   a. jih pogledate in umijete vsak dan
   b. vsakodnevna masaža z alkoholom
   c. jih vsak dan namakate eno uro
   d. nakup čevljev večje velikosti kot običajno

12. Uživanje hrane z manj mačobami zmanjša tveganje za:
   a. živčne bolezni
   b. ledvično bolezen
   c. bolezni srca
   d. očesne bolezni

13. Odrevenelost in mravljinčenje so lahko simptomi:
   a. ledvične bolezni
   b. živčne bolezni
c. očesne boleznī

d. bolezni jeter

14. Kaj od naštetega običajno Ni povezano s sladkorno boleznijo:
a. težave z vidom
b. težave z ledvicami
c. živčne težave
d. pljučne težave

_Najlepša hvala za sodelovanje!
Appendix 2 Audit on Diabetes Dependent Quality of Life (ADDQoL) and European Quality of Life-5 Dimensions (EQ-5D)
Spoštovani,

Želeli bi vam postaviti nekaj vprašanj glede vaše slapkorne bolezni.
V okviru raziskave "Kakovost življenja bohmov s slapkorno boleznijo" bi želeli dobiti sliko za Slovenijo.
Začetnino vam vašo anonimnost.
Posredovani podatki bodo uporabljeni zgolj v raziskovalne namene.
Prosimo, da z znakom "X" označite okvare ob brivi, ki najbolje predstavljajo vaš odzov na posamezno vprašanje.
Izpolnitev vprašalnika vam bo vzela okvirno dva set minut časa.
Zahvaljujemo za vaš dragocen prispevek!

Mag. Eva Turk, IZNIH za varovanje zdravja

**SPLOŠNI PODATKI**

1. Spol
   - [ ] Moški
   - [ ] Ženski

2. Leto rojstva ________

3. Vaša telesna višina _____ cm in telesna teža _____ kg

4. Poština številka ___ ___ ___ in kraj bivanja __________________________________________

5. Vaša izobražba
   - [ ] Nedokončana osnovno šola
   - [ ] Končana osnovna šola
   - [ ] Končana poklicna ali srednja šola
   - [ ] Končana višja ali visoka šola
   - [ ] Univerzitetna izobražba
   - [ ] Specializacija
   - [ ] Magisterij
   - [ ] Doktorat
6. Vaš osebni povprečni mesecni dohodek, če upoštevate neto vrednost?
☐ Do vključno 385 EUR
☐ Od 386 EUR do vključno 730 EUR
☐ Od 731 EUR do vključno 1100 EUR
☐ Od 1101 EUR do vključno 1460 EUR
☐ Nad 1461 EUR

7. Kje živite?
☐ Podnajemniško stanovanje
☐ Podnajemniška hiša
☐ Lastna hiša
☐ Pri sorodnikih/ stariših
☐ V domu za starejše občane
☐ Drugo (prosim napišite)________________________

8. Vaš zakonski stan
☐ Samski
☐ Poročen
☐ Živim v izvenzakonski skupnosti
☐ Ločen
☐ Poročen, a živim ločeno
☐ Oseval

9. Koliko časa že imate sladkorno bolezen?
☐ Do 5 let
☐ Med 6 in 10 let
☐ Več kot 11 let

10. Kateri tip sladkorne bolezni imate?
☐ Sladkorno bolezen tip 1
☐ Sladkorno bolezen tip 2

11. Kakšna je vaša raven HbA1c, čemur poljudno včasih rečemo tudi "povprečje sladkorja v zadnjih dveh mesecih"?
☐ Enaka ali nižja od 7,0%
☐ Med 7,0 in 8,5%
☐ Med 8,5 in 10%
☐ Višja od 10%

☐ V zadnjih dvanaestih mesecih so mi ga izmerili, ampak ne vem rezultata
☐ Ne vem, da bi mi ga izmerili v zadnjih dvanaestih mesecih
☐ Ne vem, da bi mi ga kadarkoli izmerili

---

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12. Kakšna je vaša vrsta zdravljenja sladkorne boleznih?

☐ Samo zdrav življenjski slog ("žileta")
☐ Tablete
☐ Insulin
☐ Drugo (prosim vpišite)

13. Kolikšen je vaš krvni tlak:

☐ Nižji od 130/80 mm Hg
☐ Med 130/80 mm Hg in 139/89 mm Hg
☐ Med kot 150/90 mm Hg in 159/99 mm Hg
☐ 160/100 mm Hg in več

☐ V zadnjih dvanajstih mesecih so mi ga izmerili, ampak ne vem rezultata
☐ Ne vem, da bi mi ga izmerili v zadnjih dvanajstih mesecih
☐ Ne vem, da bi mi ga kadarkoli izmerili

14. Ali se zdravite zaradi zvišanega tlaka?

☐ Da
☐ Ne

15. Ali so zdravite zaradi motene presnove maščob/bolesterola?

☐ Da
☐ Ne

16. Ali vam je zdravnik kdaj rekel, da vam je sladkorna bolezen poškodovala katere organske dele?

☐ Da
☐ Ne (pridite naravnost na vprašanje 24)

17. Ali vam je zdravnik kdaj rekel, da vam je sladkorna bolezen poškodovala odli?

☐ Da
☐ Ne

18. Ali ste slabovženi oziroma slopli zaradi sladkorne bolezni?

☐ Da
☐ Ne

19. Ali vam je zdravnik kdaj rekel, da vam je sladkorna bolezen poškodovala ledvice?

☐ Da
☐ Ne

20. Ali ste na dializi oziroma imate presajeno ledvicco zaradi sladkorne bolezni?

☐ Da
☐ Ne
21. Ali vam je zdravnik kdaj reklop, da vam je slabška bolezen poškodovala oživčevje nog?
   □ Da
   □ Ne

22. Ali vam je zdravnik kdaj reklop, da vam je slabška bolezen poškodovala prekruvljev nog?
   □ Da
   □ Ne

23. Ali so vam odrezali del stopala ali noge zaradi slabške bolezni?
   □ Da
   □ Ne

24. Ali ste preboleli možgansko kap?
   □ Da
   □ Ne

25. Ali ste preboleli srčno kap?
   □ Da
   □ Ne
V vsaki od spodnjih skupin treh trditev označite tisti odgovor z "X", ki najbolj ustrezno opiše vaše počutje na današnji dan.

### Pokretnost
- Pri hoji nimam nobenih težav
- Pri hoji imam nekaj težav
- Priklenjen-a sem na postelje

### Škrb Zase
- Zase poskrbim brez težav
- Pri umivanju ali oblačenju imam nekaj težav
- Ne morem se sem-a umivati ali oblačiti

### Vsakdanje Aktivnosti (npr. dela, študija, gospodinjska dela, družina, prosti čas)
- Vsakdanje aktivnosti mi ne povzročajo težav
- Vsakdanje aktivnosti opravljam z nekaj težavami
- Vsakdanjih aktivnosti nisem zmožen-na opravljati

### Bolečina/Neugodje
- Ne čutim bolečin oz. nimam občutka neugodja
- Postijo me zmerne bolečine ali občutki neugodja
- Čutim nezdravše bolečine ali skrajno neugodje

### Tesnoba/Potrost
- Nisem tesnobar na ali potrta
- Sem zmerno tesnobar na ali potrta
- Sem skrajno tesnobar na ali potrta
Da bi vam pomagali osnažiti, kako dobra ali slaba je določena zdravstvena stanja, smo izrisali lestvico, podobno termometeru.

Na njej smo v 100 označili najboljše zdravstveno stanje, ki si ga lahko zamišlite, z 0 pa najslabše zdravstveno stanje, ki si ga lahko zamišlite.

Prosimo, da na tej lestvici označite, kako dobro ali slabo je po Vašem mnenju Vaše zdravstveno stanje danes.

To naredite tako, da od črvenega pravokotnika spodaj povlecete črto do točke na lestvici, ki najbolje označuje, kako dobro ali slabo je vaše zdravstveno stanje na današnji dan.
ADDQoL

S tem vprašalnikom želimo ugotoviti, kakšna so vam zdi kakovost vašega življenja – z drugimi besedami, kako dobro ali slabo se vam zdi vaše življenje.

Prosimo, da z znakom "X" označite okenče nad izajo, ki najbolje ustreza odgovoru na posamezno vprašanje.

Najprej nas zanima, kakšno se vam trenutno zdi vaše življenje.

I) Kakovost mojega življenja je trenutno:

☐ odlčna   ☐ zelo dobra   ☐ dobra   ☐ ne dobra   ☐ slaba   ☐ zelo slaba   ☐ izjemno slaba

Zdaj pa nas zanima, kako diabetes oziroma sladkorna bolezen, občudovanje te bolezni (zdravljenje, obiski pri zdravniku, prehrana) in zapleti, ki jih morda imate, vplivajo na kakovost vašega življenja.

II) Če ne bi imel/a sladkorne bolezni, bi bila kakovost mojega življenja:

☐ neprimerno   ☐ precej boljša   ☐ malo boljša   ☐ enaka   ☐ slabša

boljša

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Prosimo vas, odgovorite na bolj podrobno vprašanja na naslednjih straneh. Vsak opis posameznega vidika življenja je sestavljen iz dveh delov, in sicer iz dela (a) in dela (b).

<table>
<thead>
<tr>
<th>V delu (a):</th>
<th>z &quot;X&quot; označite okence nad izjavo, ki najbolje opisuje kako sladkomor bolezen vpliva na ta vidik vašega življenja.</th>
</tr>
</thead>
<tbody>
<tr>
<td>V delu (b):</td>
<td>z &quot;X&quot; označite okence nad izjavo, ki najbolje opisuje pomembnost tega vidika za kakovost vašega življenja</td>
</tr>
</tbody>
</table>

1 (a) Če ne bi imel-a sladkomor bolezni, bi v svojih dejavnostih v pretem času užival-a:
- □ neprimerno bolj
- □ precej bolj
- □ malo bolj
- □ enako
- □ manj

(b) Moje dejavnosti v prostem času so zame:
- □ zelo pomembne
- □ pomembne
- □ še kar pomembne
- □ sploh mi niko pomembne

2  Ali trenutno delate, iščete delo oziroma bi radi delali?
   Da □ Če je, izpolnite (a) in (b).
   Ne □ Če ne, pojdite naprej na vprašanje 3a.

(a) Če ne bi imel-a sladkomor bolezni, bi moje delovno/poklicno življenje bilo:
- □ neprimerno
- □ precej boljše
- □ malo boljše
- □ enako
- □ slabše

(b) Delovno življenje je zame:
- □ zelo pomembno
- □ pomembno
- □ še kar pomembno
- □ sploh mi ni pomembno

3  (a) Če ne bi imel-a sladkomor bolezni, bi krajše ali daljše poti zame bile:
- □ neprimerno latje
- □ precej latje
- □ malo latje
- □ enako
telje

(b) Krajše ali daljše poti so zame:
- □ zelo pomembne
- □ pomembne
- □ še kar pomembne
- □ sploh mi niko pomembne
4 | Greje težaj na počitnice oziroma si želite biti na počitnice?
---|---
Da | ☐ će da, izpolnite (a) in (b).
Ne | ☐ će ne, pojdi to vprašanje 5a.

(a) Če ne bi imel/a sladkorone bolezni, bi moje počitnice bile:
| nesprimerno | precej boljše | malo boljše | enake | slabše |

(b) Počitnice so zame:
| zelo pomembne | pomembne | še kar pomembne | sploh mi niso pomembne |

5 | Če ne bi imel/a sladkorone bolezni, bi lahko fizično naredil/a:
---|---
| nesprimerno več | precej več | nekoliko več | enako | manj |

(b) Koliko in kaj lahko fizično naredim, je zame:
| zelo pomembno | pomembno | še kar pomembno | sploh mi ni pomembno |

6 | Ali imate družino/sorožnike?
---|---
Da | ☐ će da, izpolnite (a) in (b).
Ne | ☐ će ne, pojdi to vprašanje 7a.

(a) Če ne bi imel/a sladkorone bolezni, bi bilo moje družinsko življenje:
| nesprimerno | precej boljše | malo boljše | enako | slabše |

(b) Moje družinsko življenje je zame:
| zelo pomembno | pomembno | še kar pomembno | sploh mi ni pomembno |
Če ne bi imel ali jo imel sladkorne bolezn, bi bila moja prijateljstva in družabna življenje:

<table>
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<tr>
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<th>□</th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>neprimerno boljša</td>
<td>precej boljša</td>
<td>malo boljša</td>
<td>enaka</td>
<td>slabša</td>
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</tr>
</tbody>
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Moja prijateljstva in družabna življenje so zame:

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>zelo pomembna</td>
<td>pomembna</td>
<td>lekar pomembna</td>
<td>sploh mi niso pomembna</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Imate oziroma si želite imeti tesen osebni odnos (npr. moža/ženo, partnerja)?

Da □ Če da, izpolnite (a) in (b).
Ne □ Če ne, pojdite naravnost na vprašanje 9.

Če ne bi imel ali jo imel sladkorne bolezn, bi bila moj najtežnji osebni odnos:

<table>
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</thead>
<tbody>
<tr>
<td>neprimerno boljši</td>
<td>precej boljši</td>
<td>malo boljši</td>
<td>enak</td>
<td>slabši</td>
<td></td>
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</tbody>
</table>

Imeti tesen osebni odnos je zame:

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</thead>
<tbody>
<tr>
<td>zelo pomembno</td>
<td>pomembno</td>
<td>lekar pomembno</td>
<td>sploh mi ni pomembno</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Imate oziroma si želite imeti spolno življenje?

Da □ Če da, izpolnite (a) in (b).
Ne □ Če ne, pojdite naravnost na vprašanje 10a.

Če ne bi imel ali jo imel sladkorne bolezn, bi bilo moje spolno življenje:

<table>
<thead>
<tr>
<th>□</th>
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</thead>
<tbody>
<tr>
<td>neprimerno</td>
<td>precej boljše</td>
<td>malo boljše</td>
<td>enako</td>
<td>slabše</td>
<td></td>
</tr>
</tbody>
</table>

Spolno življenje je zame:

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</thead>
<tbody>
<tr>
<td>zelo pomembno</td>
<td>pomembno</td>
<td>lekar pomembno</td>
<td>sploh mi niso pomembno</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10 (a) Če ne bi imel-a sladkorne bolezn, bi bil moj zunanj videz:

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>neprimerno boljši</td>
<td>0</td>
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<td>precej boljši</td>
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<td>slabši</td>
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</table>

(b) Moj zunanj videz je zame:

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</tr>
</thead>
<tbody>
<tr>
<td>zelo pomemben</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>pomemben</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>še kar pomemben</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>sploh mi ni pomemben</td>
<td>0</td>
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</tbody>
</table>

11 (a) Če ne bi imel-a sladkorne bolezn, bi bila moja samozavest:

<table>
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<tr>
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</thead>
<tbody>
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<td>precej boljša</td>
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<tr>
<td>malo boljša</td>
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(b) Moja samozavest je zame:

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<tbody>
<tr>
<td>zelo pomembna</td>
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<tr>
<td>pomembna</td>
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<td>0</td>
</tr>
<tr>
<td>še kar pomembna</td>
<td>0</td>
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<tr>
<td>sploh mi ni pomembna</td>
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</tbody>
</table>

12 (a) Če ne bi imel-a sladkorne bolezn, bi bila moja motivacija:

<table>
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<tbody>
<tr>
<td>neprimerno boljša</td>
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<tr>
<td>precej boljša</td>
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<tr>
<td>malo boljša</td>
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<td>enaka</td>
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(b) Moja motivacija je zame:

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<td>zelo pomembna</td>
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<tr>
<td>še kar pomembna</td>
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<tr>
<td>sploh mi ni pomembna</td>
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</tbody>
</table>

13 (a) Če ne bi imel-a sladkorne bolezn, bi se drugi ljudje namezivali:

<table>
<thead>
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<tbody>
<tr>
<td>neprimerno</td>
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<tr>
<td>precej boljše</td>
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<tr>
<td>malo boljše</td>
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<tr>
<td>enako</td>
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<tr>
<td>slabše</td>
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</tbody>
</table>

(b) Kako se drugi ljudje odzivajo name, je zame:

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<tbody>
<tr>
<td>zelo pomembno</td>
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<tr>
<td>pomembno</td>
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<tr>
<td>še kar pomembno</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>sploh mi ni pomembno</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td></td>
<td>Če ne bi imel-a slabšo bolezn, bi moji občutki glede prihodnosti (npr. skrb, upanje) bil:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>neprimerno boljši</td>
<td>precej boljši</td>
<td>malo boljši</td>
<td>enaki</td>
<td>slabši</td>
</tr>
<tr>
<td>(b)</td>
<td>Moji občutki glede prihodnosti so zame:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>zelo pomembni</td>
<td>pomembni</td>
<td>še kar pomembni</td>
<td>sploh mi niso pomembni</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Če ne bi imel-a slabšo bolezn, bi bil moj finančni položaj:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>neprimerno boljši</td>
</tr>
<tr>
<td>(b)</td>
<td>Moji finančni položaj je zame:</td>
</tr>
<tr>
<td></td>
<td>zelo pomemben</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Če ne bi imel-a slabšo bolezn, bi bile moje življenjske razmere:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>neprimerno boljše</td>
</tr>
<tr>
<td>(b)</td>
<td>Življenjske razmere so zame:</td>
</tr>
<tr>
<td></td>
<td>zelo pomembe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Če ne bi imel-a slabšo bolezn, bi bila moja oduvajnost od drugih, kadar tega ne želim:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>neprimerno manjša</td>
</tr>
<tr>
<td>(b)</td>
<td>Da nimem oduvaj/odvaj od drugih je zame:</td>
</tr>
<tr>
<td></td>
<td>zelo pomembno</td>
</tr>
</tbody>
</table>
18 (a) Če ne bi imel/a sladkorne boleznosti, bi bila moja svoboda, da jem kakor želim:

| □ neprimerno večja | □ precej večja | □ malo večja | □ enaka | □ manjša |

(b) Svoboda, da jem, kakor želim, je zame:

| □ zelo pomembna | □ pomembna | □ še kar pomembna | □ sploh mi ni pomembna |

19 (a) Če ne bi imel/a sladkorne boleznosti, bi bila moja svoboda, da lahko pijem kakor želim (npr. sadni sok, alkohol, sladkor tople in hladne napitke):

| □ neprimerno večja | □ precej večja | □ malo večja | □ enaka | □ manjša |

(b) Svoboda, da pijem, kakor želim, je zame:

| □ zelo pomembna | □ pomembna | □ še kar pomembna | □ sploh mi ni pomembna |

Prosimo, v spodnje okvare napišete, če menite, da sladkorna bolezen, njeno obvladovanje ali z njo povezani zapleti še na kakšen drug način vplivajo na kakovost vašega življenja:
1. Za svoja slabša bolezen se vodim pri:
   - Družinskem zdravniku
   - Diabetologu
   - Obeh

2. Na sprejem v administraciji ponavadi čakam:
   - Sprožet-a sem ob dogovorenem času
   - Manj kot 15 min
   - Med 30 min in 60 min
   - Več kot 60 min

3. Na sprejem pri zdravniku ponavadi čakam:
   - Sprožet-a sem ob dogovorenem času
   - Manj kot 15 min
   - Med 30 min in 60 min
   - Več kot 60 min

4. Zdravstvena oskrba, ki so mi jo nudili zdravstveni delavci, se mi zdi:

<table>
<thead>
<tr>
<th>Odklica</th>
<th>Zelo dobra</th>
<th>Ne dobra, ne slaba</th>
<th>Slaba</th>
<th>Izjemno slaba</th>
</tr>
</thead>
</table>

5. Imam občutek, da zdravnikl včasih preslišijo kar jim povem:
   - Popolnoma se strinjam
   - Deloma se strinjam
   - Se ne strinjam
   - Ne vem

6. Imam občutek, da medicinsko sestre včasih preslišijo kar jim povem:
   - Popolnoma se strinjam
   - Deloma se strinjam
   - Se ne strinjam
   - Ne vem
   - Z njimi ne pridem v stik

7. Imam občutek, da si zdravnik vzame dovolj časa zame:
   - Popolnoma se strinjam
   - Deloma se strinjam
   - Se ne strinjam
   - Ne vem

8. Imam občutek, da si medicinska sestra vzame dovolj časa zame:
   - Popolnoma se strinjam
   - Deloma se strinjam
   - Se ne strinjam
   - Ne vem
   - Z njimi ne pridem v stik
9. Zdravstveni delavci me pogosto vključujejo v odločitve o moji zdravstveni oskrbi:

- Popolnoma se strinjam
- Deloma se strinjam
- Se ne strinjam
- Ne vsem

10. Stopnja vkljudnosti in spoštovanja, ki so jo pokazali zdravstveni delavci do mene je:

- Odlična
- Zelo dobra
- Ne dobra, ne slaba
- Slaba
- Izhajno slaba

11. Na splošno sem zadovoljen/ zadovoljna z zdravstveno oskrbo:

- Popolnoma se strinjam
- Deloma se strinjam
- Se ne strinjam
- Ne vsem

12. Imam obžutek da sam-a obvladujem svojo bolezen:

- Popolnoma se strinjam
- Deloma se strinjam
- Se ne strinjam
- Ne vsem

Prosimo, da še kakšnokoli dodatno pripombo v zvezi z vašim zadovoljstvom oskrbe upišete v spodnje okvare:

Hvala za sodelovanje.
**Original publications**


III Turk E, Prevolnik Rupel V, Tapajner A & Isola A Reliability and validity of the Audit on diabetes-dependent quality of life (ADDQoL) and EQ-5D in elderly Slovenian diabetic patients. Manuscript.


Reprinted with permission from (I) Zdreniski Vestnik, (II) Value in Health Regional Issues and (IV) HealthMED.

Original publications are not included in the electronic version of the dissertation.
1212. Tikkanen, Jani (2013) Early repolarization in the inferolateral leads of the electrocardiogram: prevalence, prognosis and characteristics


1214. Kaakinen, Pirjo (2013) Pkittäiskaissaairaiden aikuisten ohjaaksen lastu sairaalassa

1215. Pasanen, Anna Kaisa (2013) A translational study on the roles of redox molecules, cell cycle regulators and chemokine receptors as prognostic factors in diffuse large B-cell lymphoma

1216. Malo, Elina (2013) The role of low birth weight and resistin in metabolic syndrome


1219. Koskela, Sanna (2013) Granulosa cell anti-Müllerian hormone secretion in ovarian development and disease

1220. Soini, Heidi (2013) Mitochondrial DNA sequence variation in Finnish patients with maternally inherited type 2 diabetes, epilepsy and mitochondrial disease: risk and novel mutations


1222. Vuorela, Mikko (2013) Role of the RNF8, UBC13, MMS2 and RAD51C DNA damage response genes and rare copy number variants in hereditary predisposition to breast cancer

1223. Äijälä, Meiju (2013) Studies about contribution of leptin receptor in cardiovascular risk

1224. Turunen, Pauliina (2013) Natural antibodies to malondialdehyde adducts in atherosclerosis


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Eva Turk

PATIENT REPORTED OUTCOMES IN ELDERLY PATIENTS WITH DIABETES MELLITUS TYPE 2 IN SLOVENIA