The Individual Contribution and Relative Importance of Self-Management and Quality of Care on Glycaemic Control in Mexican Patients with Type 2 Diabetes

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy (PhD) in the Faculty of Medical and Human Sciences

2013

Yolanda Martinez

School of Medicine

Table of Contents

Word count 51402

List of Tables

List of Figures

List of Boxes

THE UNIVERSITY OF MANCHESTER

ABSTRACT OF THESIS submitted by Yolanda Martinez
for the degree of Doctor of Philosophy (PhD)
and entitled The Individual Contribution and Relative Importance of Self-Management and Quality of Care on Glycaemic Control in Mexican Patients with Type 2 Diabetes
Month and Year of Submission October 2013

Introduction: The global burden of diabetes can be minimised by interventions focusing on the control of glucose levels. Effective self-management and quality of care have improved diabetes outcomes such as glycaemic levels. However, few studies directly evaluate the relative importance of individual aspects of self-management and quality of care on glycaemic control. Therefore, I evaluated the individual contribution and relative importance of specific aspects of self-management and quality of care on the glycaemic control of Mexican patients with type 2 diabetes.

Methods: A longitudinal cohort study was conducted. Consecutive patients were recruited from the waiting rooms in five primary care practices in the city of Aguascalientes, Mexico (from December 2009 to April 2010). These practices are part of the largest social security institution in Mexico (the Mexican Institute for Social Security). Predictors of glycaemic control were measured from medical records and interviews with patients at baseline. Self-management was measured using four questionnaires: the Diabetes Knowledge Questionnaire (DKQ-24), the Medical Prescription Knowledge Questionnaire (MPKQ), the Summary of Diabetes Self-Care Activities (SDSCA), and the Diabetes Self Efficacy Scale. Quality of care was measured using three questionnaires and by extracting data from medical records to evaluate an index of continuity of care (MMCI) and treatment intensification. The questionnaires used were the continuity of care scale from the General Practice Assessment Questionnaire (GPAQ), the Patient–Doctor Communication Scale (PDCS), and the Patient Satisfaction with Diabetes Care scale (PSDC). Glycaemic control (HbA1c levels) was measured at two time points: baseline and six month follow-up. The main analysis was a multivariate regression model with HbA1c at six-month follow-up as the dependent variable and with self-management and quality of care as predictors and demographic and clinical factors as covariates. A secondary analysis considered the interaction between self-management and quality of care in the prediction of HbA1c at six-month follow-up using a multivariate regression model including HbA1c at baseline in the model.

Results: The multivariate linear regression model, that included all variables, was significant and explained 36 % of the variance ($P < 0.01$). Patients had lower HbA1c at follow-up if they had lower levels of HbA1c at baseline, received care at one particular practice in the city, had diabetes of shorter duration, and were prescribed monotherapy. When HbA1c at baseline was removed from the model it explained 14% of the variance ($P < 0.01$). Practice and medical prescription remained significant. In addition, lower levels of HbA1c at follow-up were related to the patient undergoing appropriate treatment intensification by their general practitioner. In the secondary analysis, the interaction showed that if treatment was not intensified, good self-managers had lower HbA1c ($P < 0.01$) but if treatment was intensified, the level of self-management had no effect.

Conclusions: Treatment intensification was the main predictor of lower HbA1c levels at follow-up. Although none of the self-management predictors was significantly related to HbA1c, an exploratory analysis of self-management/quality of care interactions showed that patients who did not receive treatment intensification but performed more self-management behaviours had lower HbA1c levels at follow-up.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Copyright

i. The author of this thesis (including any appendices and/or schedules to this thesis) owns certain copyright or related rights in it (the "Copyright") and she has given The University of Manchester certain rights to use such Copyright, including for administrative purposes.

ii. Copies of this thesis, either in full or in extracts and whether in hard or electronic copy, may be made **only** in accordance with the Copyright, Designs and Patents Act 1988 (as amended) and regulations issued under it or, where appropriate, in accordance with licensing agreements which the University has from time to time. This page must form part of any such copies made.

iii. The ownership of certain Copyright, patents, designs, trade marks and other intellectual property (the "Intellectual Property") and any reproductions of copyright works in the thesis, for example graphs and tables ("Reproductions"), which may be described in this thesis, may not be owned by the author and may be owned by third parties. Such Intellectual Property and Reproductions cannot and must not be made available for use without the prior written permission of the owner(s) of the relevant Intellectual Property and/or Reproductions.

iv. Further information on the conditions under which disclosure, publication and commercialisation of this thesis, the Copyright and any Intellectual Property and/or Reproductions described in it may take place is available in the University IP Policy (see http://www.campus.manchester.ac.uk/medialibrary/policies/intellectual-property.pdf), in any relevant thesis restriction declarations deposited in the University Library, The University Library's regulations (see http://www.manchester.ac.uk/library/aboutus/regulations) and in The University's policy on presentation of Theses.

List of Abbreviations

BDI	Beck Depression Inventory
BMI	Body mass index
BNF	British National Formulary
CDSMP	Chronic Disease Self-Management Programmes
CONACYT	National Council on Science and Technology [Consejo Nacional de Ciencia y Tecnología]
CONEVAL	National Council for the Evaluation of Social Development Policy [Consejo Nacional de Evaluación de la Política de Desarrollo Social]
CONSORT	Consolidated Standards of Reporting Trials
DKQ-24	Diabetes Knowledge Questionnaire 24 items
EASD	European Association for the Study of Diabetes
EUROPEP	European Task Force on Patient Evaluations on General Practice Care
FBG	Fasting blood glucose
GNI	Gross national income
GP	General practitioner
GPAQ	General Practice Assessment Questionnaire
IDF	International Diabetes Federation
IOM	Institute of Medicine
IQR	Interquartile range
mg/dl	Milligrams per decilitre
MISS	Mexican Institute for Social Security [Instituto Mexicano del Seguro Social – IMSS]
MMCI	Modified Modified Continuity Index
mmol/l	Millimole per litre
MPKQ	Medical Prescription Knowledge Questionnaire
PDCS	Patient–Doctor Communication Scale
PEMEX	Mexican Petroleum [Petróleos Mexicanos]
PSDC	Patient Satisfaction with Diabetes Care
RCT	Randomised controlled trial
SD	Standard deviation
SDSCA	Summary of Diabetes Self-Care Activities
SMBG	Self-monitoring of blood glucose
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization

Acknowledgments

I would like to express my most sincere gratitude to my supervisors, Peter Bower, Stephen Campbell, Mark Hann, and Linda Gask, as well as my advisor, Anne Rogers. I am very grateful for their advice, constructive comments and suggestions as well as their support.

I would like to thank to all the people in the Primary Care group who were always kind and made me feel at home. I was delighted to spend time with my colleagues and friends during my stay in Manchester, Huixing Zhang, Nik Sherina Hanafi, Julia Segar, Julia Hiscock, and Donna Bramwell.

I am very grateful to the participants whose contribution was very important and gave the opportunity to know more about diabetes management in Mexico. The interviewers were a key part of data collection and I am very grateful to all of them: Renata Isabel Galindo Andrade, América Fabiola Aguiñaga Rincón, Brenda Berenice Valenciano Martínez, Enrique Cardona, Karina Alejandra Pedroza García, José Luis Juárez Ruiz Esparza, Laura Carolina Soto Ham, and María Angélica Alonso Álvarez.

I would like to thank to the Consejo Nacional de Ciencia y Tecnología (CONACYT) for my scholarship and the Secretaría de Educación Pública (SEP) for a complementary scholarship. The Instituto Mexicano del Seguro Social provided all the information necessary for data collection, and it is my place of work. My boss, José de Jesús Valdivia Martínez, was very supportive and helpful, and I am very grateful to him.

My family (husband, mum, dad and brother), relatives and friends were always cheerful and supportive during my PhD. Thanks to all of them and especially to my loving and supportive husband David.

Dedication

To God

The author

I have a degree in Psychology from the Universidad de Guadalajara (1998) and a masters in Health Systems from the Universidad Autónoma de Aguascalientes (2003). After I finished my degree, I started to work as a research assistant in various projects, some of them about diabetes.

I also worked as a tutor at the Universidad Autónoma de Aguascalientes in both undergraduate and postgraduate courses in health sciences (2003–2007). I formally joined the Instituto Mexicano del Seguro Social in 2006. I have been supervising dissertations in the speciality of family medicine since then. I was part of the ethics committee and I continue to review protocols for the committee.

I started the PhD in 2008 at the University of Manchester and I received a scholarship from the Consejo Nacional de Ciencia y Tecnología (CONACYT).

Chapter 1
Introduction

Mexico is among the ten countries with the highest number of people with diabetes (estimated at 10.3 million for 2011 and predicted to reach 16.4 million by 2030) (IDF 2011d). Diabetes is one of the leading causes of disease burden and death in Mexico along with high blood glucose (Stevens et al. 2008). A key goal of diabetes care is to improve glycaemic control through the reduction of blood glucose levels. Glycaemic control can minimise diabetes complications and premature mortality (UKPDS 1998a; UKPDS 1998b). Some intervention strategies have been focused on the reduction of blood glucose through conventional and intensive medical treatment being cost-effective in adding years of life to the population (Salomon et al. 2012). Other interventions have reported that effective self-management (Deakin et al. 2005; Gary et al. 2003; Norris et al. 2001; Sarkisian et al. 2003) and quality of care (Knight et al. 2005; Piatt et al. 2006; Pimouguet et al. 2011; Renders et al. 2001; Shojania et al. 2006) improve diabetes outcomes. However, there are no studies directly evaluating the relative importance of individual aspects of self-management and quality of care on glycaemic control.

I identify and evaluate the individual contribution and relative importance of specific aspects of self-management and quality of care on the glycaemic control of adult patients with type 2 diabetes. I focus on type 2 diabetes because it is more frequent accounting for 90% of all cases of diabetes and the management of type 2 diabetes is different from other types of diabetes. Adults aged 40 or more years were selected because type 2 diabetes is usually diagnosed at this age.

Through a literature review, self-management and quality of care are defined. These definitions provide the basis to identify the individual aspects of self-management and quality of care that are measured in this Thesis.

Key self-management and quality of care variables were identified through a literature review from evidence-based studies. Some of these key self-management and quality of care variables were selected to include in this Thesis because it was feasible to measure them. Aspects of self-management included in this Thesis are general diabetes knowledge and medical prescription knowledge, diabetes self-efficacy, and self-

management behaviours. These self-management aspects were measured by patient self-report. Aspects of quality of care included in this Thesis are continuity of care, treatment intensification, patient–doctor communication, and patient satisfaction with diabetes care. Treatment intensification was extracted from medical records. Patient reports were used to measured patient–doctor communication, and patient satisfaction with diabetes care. Two methods were used to measure continuity of care: patient reports and medical record extraction.

The empirical evidence was collected in the context of primary healthcare in the city of Aguascalientes, Mexico, from five primary care practices from the largest social security institution in Mexico (Mexican Institute for Social Security, MISS).

The fieldwork for this study was conducted in the city of residence and workplace of the author. The National Council on Science and Technology (CONACYT) provided the scholarship to complete this PhD. CONACYT is a public and decentralised organisation of the Mexican Government, contributing to the development of knowledge and technology in the solution of key priorities facing Mexico. One of these priorities is diabetes as a long-term condition with a clinical, social, and economic burden for Mexico.

1.1 Research questions

There were six research questions in this Thesis:

> *RQ1. What are the demographic, clinical, self-management, and quality of care characteristics of patients with type 2 diabetes in primary care?*
>
> *RQ2. What demographic and clinical factors are related to self-management and quality of care in primary care?*
>
> *RQ3. What is the relationship within and between self-management and quality of care in primary care?*
>
> *RQ4. What demographic, clinical, self-management, and quality of care factors are related to glycaemic control at baseline in primary care?*

RQ5. What demographic, clinical, self-management, and quality of care factors predict glycaemic control at six-month follow-up in primary care?

RQ6. What is the relative importance of self-management and quality of care in the prediction of glycaemic control at six-month follow-up in primary care?

1.2 Research design and methodology

I used a prospective cohort study with six-month follow-up.

1.3 Structure of the Thesis

I provide a literature review in the first part of this Thesis, over five chapters (Chapters 2–6), which describes the context of the study and provides definitions of key terms and concepts relating to diabetes, quality of care, and self-management. A short chapter (Chapter 7) then is a summary of Part One of the Thesis and sets out the research questions to be answered in the second part of the Thesis. The data collection and analysis methods are then detailed, and the results presented in Part Two. Finally, the, results are discussed in Part Three: 1) showing the original contribution of the research, 2) showing the implications for clinical practice and policy, and 3) offering recommendations for future research. The content of each of the nine subsequent chapters is summarised below.

Chapter 2 describes Mexico in terms of its geographic and socio-demographic characteristics, including the county where data collection was performed (Aguascalientes).

Chapter 3 includes information about the Mexican healthcare system and its performance, together with a description of primary care in the MISS from where the participating sample of practices was recruited.

Chapter 4 defines and describes diabetes in terms of its diagnosis, treatment, comorbidity, and global burden.

Chapter 5 outlines and critiques definitions of self-management and quality of care, and the process used to select the individual aspects of self-management and quality of care used in this Thesis. This chapter also includes a review of empirical literature on self-management and quality of care in Mexico.

Chapter 6 presents a review of current empirical evidence about the individual contribution and relative importance of both self-management and quality of care in the glycaemic control of patients with type 2 diabetes from a systematic review.

Chapter 7 is a summary of research problem and research questions of this Thesis.

Chapter 8 is a description of the methodologies used to collect and analyse data in the cohort study in relation to each of the research questions.

Chapter 9 contains the results of the cohort study including a description of the sample, followed by an evaluation of predictors of glycaemic control at baseline and follow-up.

Chapter 10 contains a discussion of the main results of the cohort study, strengths and limitations of the research, and a critical discussion of the implications for policy, practice, and future research in this area.

Chapter 2
Mexico

2.1 Introduction

The aim of this chapter is to put this research in context and to help the reader understand important characteristics of Mexicans. Participants in this Thesis are patients with type 2 diabetes living in the city of Aguascalientes. Demographic characteristics will be described for the participants in this Thesis in Chapter 9 and these characteristics are part of four research questions: *RQ1, RQ2, RQ4 and RQ5* (included on pages 19 and 20).

This chapter starts by describing the geographic and political boundaries of Mexico, and then the socio-demographic and health characteristics of the Mexican population. This section is followed by a description of Mexican government.

The key points from this chapter are summarised in Box 2.1.

Box 2.1 Key points from Chapter 2

- Mexico is located in Central America and covers an area of almost 2 million km^2
- Mexico is governed as a federal republic with 32 counties
- Total population is around 112 million
- Most people (77%) live in urban areas
- Literacy is around 91.5%
- The proportion of people meeting criteria for poverty is around 44%
- The Mexican Government has three branches: executive, legislative, and judiciary

2.2 Geography and socio-demographic characteristics of Mexico

Mexico is located in Central America and the official name of the country is the United Mexican States (United Nations 2012). The first language is Spanish. Mexico is an upper-middle-income country based on The World Bank Group definition, having a gross national income per capita of 9240 US dollars (The World Bank Group 2012a;The World Bank Group 2012c). Mexico borders the United States of America (USA) to the north and Guatemala and Belize to the south and covers almost 2 million km^2. Mexico has 32 counties (Figure 2.1). The county of Aguascalientes is highlighted in the map in Figure 2.1 because the fieldwork for this Thesis was performed there.

Figure 2.1 Map of the United Mexican States

Source: (INEGI 2012b)

The Mexican Government performs a census every 10 years. In 2010, the total population of Mexico was around 112 million (male 55 million and female 57 million) and age groups were: 0–9 years (21,575,859), 10–19 years (21,966,049), 20–59 years (48,382,189), 60 years and more (19,015,035), and unspecified age (1,397,406). The percentage of the population living in urban and rural areas was 77% and 23% respectively. Twenty one of the 32 counties had more than 70% of people living in urban areas. There were six counties with almost half of population living in rural areas (Chiapas, Guerrero, Hidalgo, Oaxaca, Tabasco, and Zacatecas) (INEGI 2012a).

Table 2.1 shows information about total population (urban and rural areas), land area, municipalities, and poverty by county. The percentage of land area ranges from 0.1% (Federal District) to 12.6% (Chihuahua) per county. Counties have from five (Baja California) to 570 municipalities (Oaxaca). The number of municipalities does not correspond to the geographic size of every county. For example, Chihuahua (67

municipalities) is almost three times the size of Chiapas, but Chiapas has 570 municipalities. Almost half of the total population were living in the most densely populated counties: Distrito Federal, Jalisco, County of Mexico, Puebla, and Veracruz (INEGI 2012a). Aguascalientes is a small county (land area is 0.3%) with 11 municipalities and more people are living in urban areas (81%) compared to the national percentage (77%).

National literacy (defined as people older than 15 years able to read and write) was 92.3% (INEGI 2012a). The national census provided the level of education in people 12 years and older who were categorised in five-year groups. I included people 40 years and older, therefore, this group is described from the national census in terms of its level of education. The group of people 40 years and older included 31,952,991. The level of education in this group was: without any education 13.8%, nursery school 0.5%, primary school 41.9%, secondary school 16.3%, technical school 1%, high school and higher 26%, and unspecified 0.5% (INEGI 2012a).

The National Council for the Evaluation of Social Development Policy (CONEVAL) defined poverty as those with insufficient income to satisfy basic needs and with at least one of the following social deficits: educational gap, access to healthcare, access to social security, home quality and spaces, access to basic services at home, and access to food (CONEVAL 2012). These social deficits are related to the social determinants of health because both can be responsible for health inequalities. Social determinants of health are defined by the World Health Organization as 'the conditions in which people are born, grow, live, work and age, including the health system … and shaped by the distribution of money, power and resources at global, national and local levels' (WHO 2012b).

CONEVAL has defined each of these social deficits but two are highlighted here as they directly address key themes within the context of this Thesis in relation to access to healthcare and access to social security. These concepts were chosen because healthcare can be provided by social security institutions and social security includes more services. Access to healthcare means that people are registered to a healthcare institution. People who have access to social security have additional benefits (i.e. a pension after retirement). Patients in this Thesis received healthcare from MISS, which is the biggest social security institution in Mexico.

Poverty is an important issue for this Thesis because it is related to self-management. It has been suggested that self-management can be used by people who do not have access to healthcare. Therefore, self-management can be 'the most dominant form of primary care' contributing to poverty alleviation (WHO and SEARO 2009). One of the social deficits in poverty is related to education. I explore demographic characteristics of patients with type 2 diabetes included in four research questions: *RQ1, RQ2, RQ4 and RQ5* (included on pages 19 and 20).

Extreme and moderate poverty were found in 11.4% and 34.9%, respectively, of people across Mexico in 2010. Extreme poverty ranged from 1.9% (Nuevo Leon) to 38.3% (Chiapas) across the counties. Moderate poverty ranged from 19.2% (Nuevo Leon) to 50.6% (Tlaxcala) (CONEVAL 2010). Figure 2.2 shows the distribution of poverty with the lowest percentages in the north of Mexico; a mix of low and high percentages in the centre and south-east; and the highest percentages in the south-west. Extreme poverty in Aguascalientes (3.7%) was lower compared to the national percentage (11.4%) and moderate poverty was very similar between Aguascalientes and the national data (around 34%).

Table 2.1 Geography and socio-demographic characteristics of the 32 counties of Mexico

Counties	Total population Urban / Rural* %	Land area %	Municipalities	Multidimensional poverty† %	
				Extreme poverty	Moderate poverty
National	112 336 538 77 / 23	100	2456	11.4	34.9
Aguascalientes	1 184 996 81 / 19	0.3	11	3.7	34.5
Baja California	3 155 070 92 / 8	3.7	5	3.5	28.6
Baja California Sur	637 026 86 / 14	3.8	5	4.6	26.3
Campeche	822 441 75 / 25	2.9	11	13.6	36.7
Chiapas	4 796 580 49 / 51	3.8	118	38.3	40.2
Chihuahua	3 406 465 85 / 15	12.6	67	6.6	32.6
Coahuila de Zaragoza	2 748 391 90 / 10	7.7	38	3.0	25.0
Colima	650 555 89 / 11	0.3	10	2.5	32.2
Distrito Federal	8 851 080 99.5 / 0.5	0.1	16	2.2	26.5
Durango	1 632 934 69 / 31	6.3	39	10.3	41.0
Guanajuato	5 486 372 70 / 30	1.6	46	8.4	40.1

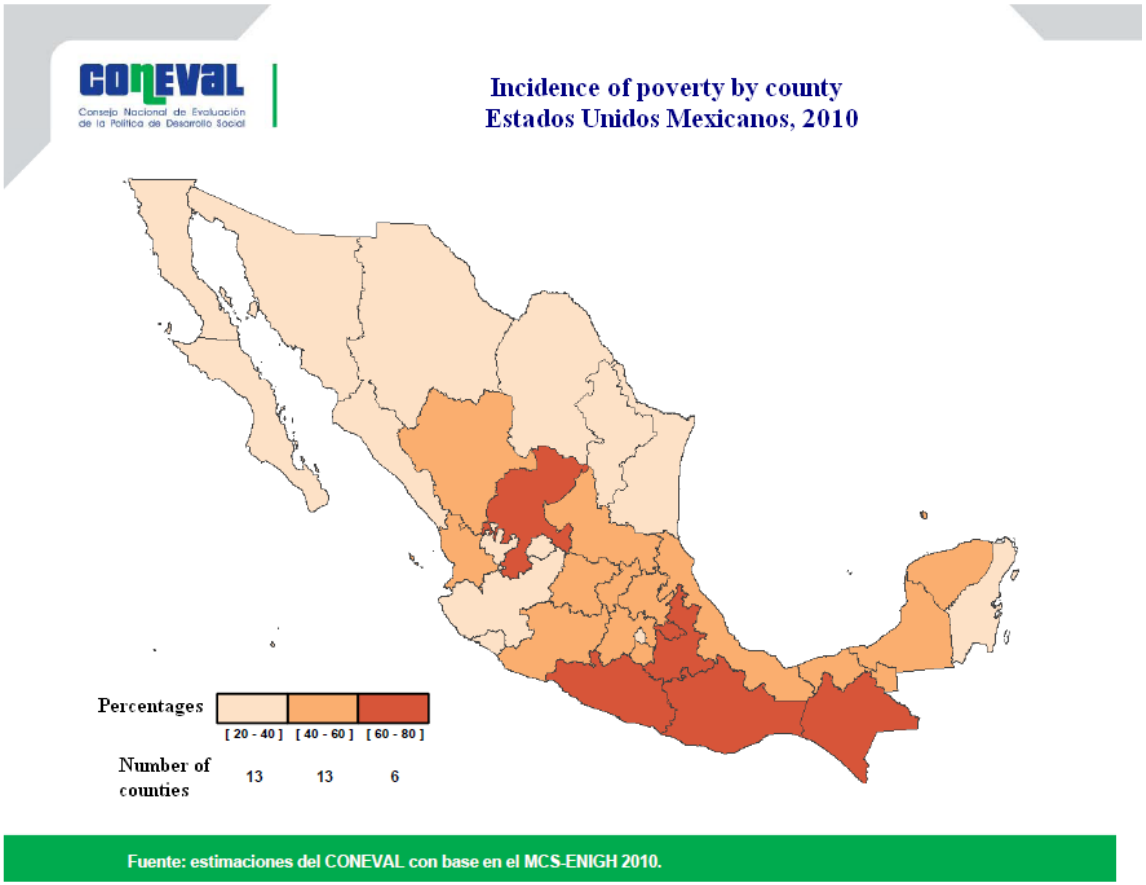
Counties	Total population Urban / Rural* %	Land area %	Municipalities	Multidimensional poverty† % Extreme poverty	 Moderate poverty
Guerrero	3 388 768 58 / 42	3.3	81	31.6	36.0
Hidalgo	2 665 018 52 / 48	1.1	84	13.5	41.4
Jalisco	7 350 682 87 / 13	4.0	125	5.2	31.7
County of Mexico	15 175 862 87 / 13	1.1	125	8.6	34.4
Michoacán de Ocampo	4 351 037 69 / 31	3.0	113	13.5	41.3
Morelos	1 777 227 84 / 16	0.3	33	7.0	36.6
Nayarit	1 084 979 69 / 31	1.4	20	8.2	33.1
Nuevo Leon	4 653 458 95 / 5	3.3	51	1.9	19.2
Oaxaca	3 801 962 47 / 53	4.8	570	29.8	37.6
Puebla	5 779 829 72 / 28	1.7	217	16.7	44.5
Queretaro	1 827 937 70 / 30	0.6	18	7.4	34.0
Quintana Roo	1 325 578 88 / 12	2.2	9	6.3	28.3
San Luis Potosi	2 585 518 64 / 36	3.1	58	15.5	37.1

Counties	Total population Urban / Rural* %	Land area %	Municipalities	Multidimensional poverty† %	
				Extreme poverty	Moderate poverty
Sinaloa	2 767 761 73 / 27	2.9	18	5.4	31.1
Sonora	2 662 480 86 / 14	9.2	72	5.3	28.5
Tabasco	2 238 603 57 / 43	1.3	17	13.6	43.7
Tamaulipas	3 268 554 88 / 12	4.1	43	5.6	33.7
Tlaxcala	1 169 936 80 / 20	0.2	60	10.0	50.6
Veracruz de Ignacio de la Llave	7 643 194 61 / 39	3.7	212	19.3	39.2
Yucatán	1 955 577 84 / 16	2.2	106	11.7	36.8
Zacatecas	1 490 668 59 / 41	3.8	58	10.8	49.4

* Urban area was defined as a town with a population of ≥2500 people. Rural area was defined as a locality with a population of less than 2500 people (INEGI 2012a].

† Poverty was measured using two dimensions: income and social lacks (educational gap, access to healthcare, access to social security, home quality and spaces, access to basic services at home, and access to food). Then extreme poverty was defined as population with income below the minimum wellbeing line and with at least three social lacks. Moderate poverty was defined as population with income below the wellbeing line and with at least one social lack (CONEVAL 2012). Source of data: (CONEVAL 2010).

Figure 2.2 Distribution of poverty in Mexico



Source: (CONEVAL 2011).

2.3 Mexican government

Mexico is governed as a democratic and federal republic organised in three branches: executive, legislative, and judiciary. Although this organisation is common among constitutional governments, every country gives a different balance to each branch (Cameron and Falleti 2005). For example, presidential systems like Mexico are characterised by a separation of purpose in every branch while parliamentary systems like the British systems are seen as unitary (Cameron and Falleti 2005; Gerring et al. 2009). Minority governments are more frequent in presidential systems (Samuels 2007).

In Mexico, the executive branch is represented by the President of the United Mexican States, who is assisted by the Secretaries of State (including the Secretary of Health). The President is elected by the Mexican adult population (≥18 years old) for one six-year term without re-election. The legislative is the Congress of the Union and incorporates two chambers: the Chamber of Senators and the Chamber of Deputies. There is a local congress in each county as well. Members of the local congress are deputies. A local congress is independent from the Congress of the Union. Both the Congress of the Union and a local congress can propose new laws or changes to current laws. These bills become laws when the President of Mexico (in the case of the Congress of the Union) or the governors (in the case of a local Congress) approve them (Canal del Congreso 2011).

The judiciary is organised by four groups: the Supreme Court of Justice, the Electoral Tribunal, Collegiate and Circuit Tribunals, and District Courts. The judiciary interprets and applies the law (Presidencia de la Republica 2012).

The bills proposed by a local congress apply only in the county where the bill was proposed. However, bills proposed by the Congress of the Union apply to every county. Laws are based on the Political Constitution of the United Mexican States (Estados Unidos Mexicanos 1917). The constitution includes laws about social rights. One social right is protection in health and it is included in the fourth article:

> Every person has the right to health protection. The law will define the basis and methods to access healthcare services. The law will establish the congruency between the Federation and the federative entities [counties]

> about general health issues. This will be in accordance with section XVI, article 73 in this Constitution (Estados Unidos Mexicanos 1917, pp. 5–6).

A core focus in this Thesis is quality of care, and the emphasis is on usually having access to the same general practitioner in primary care.

General health issues, including access to healthcare, are established by the President, the Congress of the Union, and the Secretary of Health. There is a description of the Mexican healthcare system in Chapter 3.

2.4 Summary

Mexico is located in Central America and covers almost 2 million km^2. Mexico is divided in 32 counties. The total population is around 112 million with most people living in urban areas (77%), with 91.5% defined as literate, and 44.2% living in poverty. Mexico is governed as a federal republic including three branches: executive, legislative, and judiciary. The Mexican constitution includes the legal right of access to healthcare services and to health protection. The next chapter covers the health characteristics of Mexicans and the healthcare system in Mexico.

Chapter 3
Health and Mexican healthcare system

3.1 Introduction

This chapter describes the health of the Mexican population and the structure of the Mexican healthcare system to set the context for understanding the quality of care and self-management initiatives, the general practitioners' role, and patients' features. This chapter also shows how diabetes is a key issue and the leading cause of death, and so is a policy and health priority in Mexico.

The chapter starts by describing the health characteristics of the adult Mexican population. This is then followed by a description of the organisation of the Mexican healthcare system, followed by a critique of the performance of the Mexican health system by the World Health Organization (WHO). There is a section describing the institution at which this Thesis was carried out, the Mexican Institute of Social Security. The final sections are about comparisons between the primary care systems of the United Kingdom (UK) and Mexico. The key points from this chapter are summarised in Box 3.1.

Box 3.1 Key points from Chapter 3

- National life expectancy at birth in Mexico is higher than the average of upper-middle-income countries (75 years vs. 72 years)
- National prevalence of main long-term conditions and risk factors is as follows: diabetes 7.0%, hypertension 15.4%, hypercholesterolemia 8.6%, overweight 42.5% (men) and 37.4% (women); and obesity 24.2% (men) and 34.5% (women)
- Health services in Mexico are provided by a range of institutions
- MISS is the biggest social security institution in Mexico
- General practitioners are the first point of contact and gatekeepers of the Mexican primary care system
- General practitioners in Mexico provide primary care in consultations lasting 15 minutes

3.2 Health characteristics of Mexicans

Life expectancy for upper-middle-income countries was reported by 49 of the 53 such countries in 2010 (The World Bank Group 2012b) as being an average of 72 years. The lowest life expectancy was 51 years in Angola and the highest value was 79 years in Costa Rica. Life expectancy in Mexico was 77 years. Table 3.1 shows life expectancy in each Mexican county for women and men (Secretaria de Salud 2007).

In 2006, the National Institute of Public Health conducted a national survey of health and nutrition across all counties in Mexico. The survey showed the prevalence of the main long-term conditions in Mexican adults (diabetes, hypertension, and hypercholesterolemia) as well as data on proportions of patients with risk factors (overweight or obesity) (Olaiz-Fernandez et al. 2006). National prevalence of these conditions is included in Table 3.1: diabetes 7.0% (ranging from 5.1% in Guerrero to 9.8% in Tamaulipas); hypertension 15.4% (ranging from 9.4% in Guerrero to 20.4% in Baja California); and hypercholesterolemia 8.6% (ranging from 4.1% in Oaxaca and Zacatecas to 16.2% in Baja California). Between 2000 and 2006, the prevalence of these conditions rose as follows: diabetes from 5.8% to 7%, hypertension from 12.5% to 15.4%, and hypercholesterolemia from 6.4% to 8.5% (Olaiz et al. 2003; Olaiz-Fernandez et al. 2006). I focus on diabetes, which is the primary cause of death in Mexico with more than 60,000 deaths and 400,000 new cases per year (Secretaria de Salud 2008).

The national survey also evaluated proportions of patients who are overweight and obese using body mass index (BMI) (weight in kilograms divided by height in metres squared). BMI was classified based on recommended categories by the WHO: underweight (BMI <18.5), normal range (BMI 18.5–24.9), overweight (BMI 25.0–29.9), and obese (BMI ≥30.0) (Olaiz-Fernandez et al. 2006). Nationally, the percentage of the adult population that were overweight was 42.5% in men and 37.4% in women (ranging from 38.9% in Baja California and Guanajuato to 47.3% in Aguascalientes for men, and from 30.7% in San Luis Potosí and Sonora to 43.5% in the County of Mexico for women). The national percentage of obesity in adults was 24.2% in men and 34.5% in women (ranging from 17.1 in Chiapas to 32.1% in Tamaulipas for men and from 25.4% in Guerrero to 46.9% in Sonora for women). The percentage of people overweight or obese has also increased over time in women from 61% in 1999 to 69.3%

in 2006 and men from 59.7% in 2000 to 66.7% in 2006 (Olaiz-Fernandez et al. 2006). The WHO suggests that the increasing prevalence of these conditions in low- and middle-income countries is because their population is more exposed to risk factors (e.g. physical inactivity and unhealthy diet), less exposed to prevention strategies, and has less access to effective and equitable healthcare services (WHO 2011a).

People in poverty may be the most exposed population to risk factors because they do not usually have access to healthcare and healthy food (CONEVAL 2012). In Mexico, the percentage of poverty, including extreme and moderate poverty, was 46.5% in 2010. Poverty is a social determinant of health, increasing child and adult mortality (Marmot 2005). For example, the highest child mortality is related to the lowest socioeconomic level and the highest adult mortality is related to the lowest level of education (Marmot 2005).

The next section describes the Mexican healthcare system including three main providers of health services and the people who access each type of provider.

Table 3.1 Health characteristics of Mexican adults

Counties	Life expectancy at birth*		Diabetes†	Hypertension†	Hypercholesterolemia†	Overweight†		Obesity†	
	Males	Females				M	F	M	F
Aguascalientes	73.7	78.4	5.9	20.1	7.6	47.3	38.2	20.3	30.9
Baja California	74.4	78.8	8.7	20.4	16.2	38.9	33.7	25.5	36.8
Baja California Sur	73.5	78.5	6.1	18.1	11.7	43.5	37.4	28.2	43.5
Campeche	72.5	77.3	6.0	12.5	7.9	43.9	32.7	26.6	45.5
Coahuila de Zaragoza	73.8	78.5	7.1	14.4	7.0	43.6	33.4	25.2	39.7
Colima	73.5	78.2	8.4	19.3	10.3	45.0	32.4	25.3	34.8
County of Mexico	73.4	78.3	7.4	16.0	9.2	43.2	43.5	25.8	31.5
Chiapas	71.2	76.5	5.4	13.0	9.0	41.4	36.6	17.1	31.0
Chihuahua	73.9	78.6	6.3	13.6	7.0	42.9	37.4	23.0	39.4
Distrito Federal	74.2	78.9	8.9	18.7	11.8	43.8	41.2	26.0	34.2
Durango	72.9	77.8	7.4	18.5	7.9	46.0	33.7	22.2	45.3
Guanajuato	72.9	77.7	5.6	17.7	5.5	38.9	36.3	25.4	38.1
Guerrero	71.4	76.8	5.1	9.4	6.3	39.0	34.0	25.8	25.4
Hidalgo	72.0	77.3	7.1	13.5	7.5	40.7	41.5	19.1	27.4
Jalisco	73.5	78.3	7.9	17.8	8.7	40.2	36.5	23.5	36.7
Michoacán de Ocampo	72.6	77.5	5.8	13.9	6.3	41.7	36.4	26.1	34.4

Counties	Life expectancy at birth*		Diabetes†	Hypertension†	Hypercholesterolemia†	Overweight†		Obesity†	
	Males	Females				M	F	M	F
Morelos	73.3	78.1	6.3	12.9	7.0	45.3	39.0	21.0	31.3
Nayarit	72.9	77.8	7.2	19.4	8.2	45.9	31.2	23.7	39.5
Nuevo Leon	73.9	78.7	6.4	12.2	6.8	40.7	32.2	28.3	40.3
Oaxaca	71.4	76.7	5.2	13.0	4.1	40.4	35.2	18.7	26.7
Puebla	72.3	77.6	6.3	11.8	5.8	45.6	40.2	17.7	29.6
Queretaro	73.0	77.9	5.3	11.5	5.3	44.0	33.5	21.9	27.1
Quintana Roo	73.3	78.1	6.7	18.2	14.3	39.5	40.4	31.2	37.4
San Luis Potosi	72.5	77.4	6.2	14.5	4.5	46.1	30.7	19.7	39.4
Sinaloa	73.1	77.9	5.5	14.9	7.7	43.5	41.3	24.6	32.0
Sonora	73.7	78.4	6.5	19.9	11.5	40.1	30.7	27.4	46.9
Tabasco	72.4	77.4	6.2	15.0	11.3	40.4	34.7	28.8	41.2
Tamaulipas	73.5	78.2	9.8	17.8	11.0	41.5	33.3	32.1	39.3
Tlaxcala	72.9	78.0	6.7	12.4	5.9	46.4	38.7	21.6	33.4
Veracruz de Ignacio de la Llave	72.0	77.2	8.6	13.3	10.0	45.7	35.0	21.8	31.7
Yucatán	72.5	77.4	5.4	12.6	9.1	40.0	39.2	30.8	37.8
Zacatecas	72.6	77.4	5.9	16.3	4.1	41.1	37.6	19.4	34.1

* Source: Secretaria de Salud 2007; †Source: Olaiz-Fernandez et al. 2006; M=males; F=females; Figures are percentages.

3.3 Mexican healthcare system

The Mexican healthcare system provides health services through the Ministry of Health, social security institutions, and private services. Every provider has their own facilities (e.g. hospitals, medical practices, and pharmacies), staff (e.g. doctors and nurses), and funding (Secretaria de Salud 2007). Figure 3.1 shows a block diagram of the Mexican healthcare system.

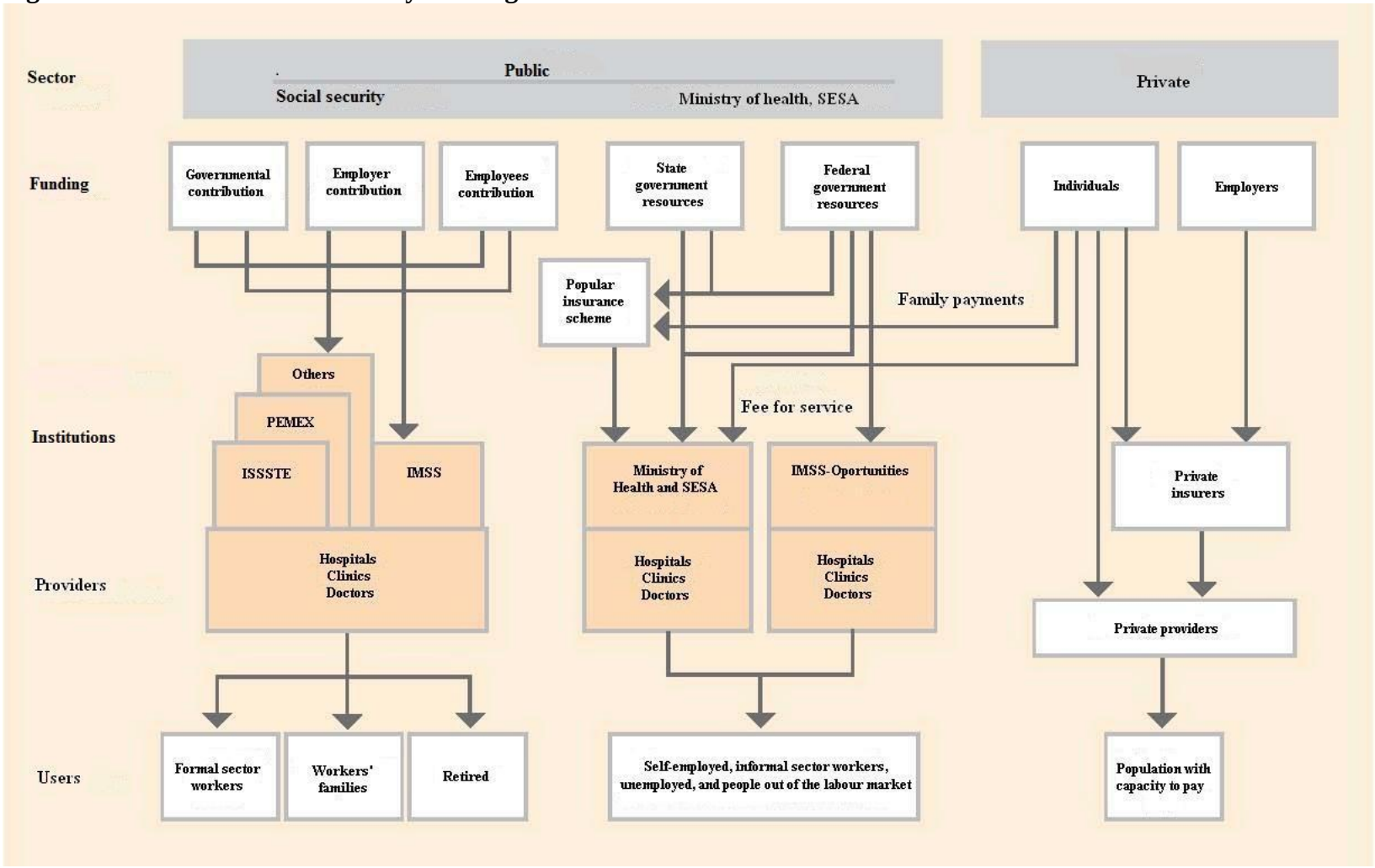
The Ministry of Health provides care to the self-employed, informal sector workers, the unemployed, and people out of the labour market. These people do not have access to a social security institution and are more likely to be in poverty. The Ministry of Health provides primary and specialist care in its own practices and hospitals. Most of the people (99.4%) who receive health services from the Ministry of Health do not pay, and the government provides the funding (Secretaria de Salud 2012). All the staff are salaried workers.

Social security institutions provide care for workers and their families who receive full coverage of health services in primary and specialist care. Funding comes from employers, employees, and the government, for example, employers can contribute up to 20.4% of minimum wage, employees up to 2.75%, and government up to 14.5% (Oxley et al. 2005). The main social security institutions are MISS, covering most of the insured workers, Institute of Security and Social Services for State Workers (ISSSTE) covering government workers, and others, for example PEMEX, covering workers in the Mexican petroleum company. Social security institutions also have salaried workers.

The third provider of health services is the private sector. These services are available to anyone who has the capacity to pay for their health services. Patients can self-refer to private primary, elective, and specialist care. Private healthcare providers are paid by fee for their services. It is usual for patients to attend more than one provider. For example, patients registered to a social security institution also attend private providers. This means that patients pay out-of-pocket to receive private care.

There was a performance evaluation of the Mexican healthcare system by the WHO in 2000 and the results are included in the following section.

Figure 3.1. Mexican healthcare system organisation



Original diagram is in Spanish (see Appendix 3.1, p.314).

3.4 Performance of Mexican healthcare system

The WHO report presented a league table showing the overall performance of health systems for 191 members states (WHO 2000). This table included a rank and an index of the overall performance of each health system. The index was calculated using three variables (input and output of health systems and a non-health-system determinant of health). Input was the total health expenditure per capita. Output was a composite index including health, health inequality, level of responsiveness, distribution of responsiveness, and fairness in financing. The non-health-system determinant was educational attainment. Mexico was ranked 61 out of the 191 member states, with an index of 0.755. Mexico performed similarly to a mix of upper-middle-income, low-middle-income, and high-income countries according to the World Bank classification (The World Bank Group 2011), e.g. Seychelles (upper middle income), Paraguay (lower middle income), and Republic of Korea (high income). Countries in the top 10 were from Europe and Asia (e.g. France, Italy, and Singapore) and countries in the bottom 10 were mainly from Africa (e.g. Sierra Leone, Central African Republic, and Democratic Republic of the Congo) (Tandon et al. 2000).

The Mexican Institute of Social Security is the biggest social security institution in Mexico; it is the place of data collection for this Thesis and is described in following section.

3.5 Mexican Institute of Social Security

The Mexican Institute of Social Security provides healthcare for most salaried private-sector workers and their families in Mexico, covering approximately 35 million people (INEGI 2010). People registered in the MISS receive full coverage of medicines, examinations, urgent and emergency care, operations, rehabilitation, and social care. MISS has its own facilities and staff to deliver these services. Primary care services are delivered by general practitioners (GP) and other staff (e.g. nurses and social workers) providing health education, disease detection, and preventive and curative care (Ruiz-Hernandez et al. 2005).

MISS was the first health institution in Mexico, providing primary care from 1959. MISS is the first and most important primary care provider in Mexico (PAHO 2007).

Ruiz-Hernandez et al. (2005) provides a description of healthcare services offered by MISS. Primary care represents approximately 85% of all health services in MISS (65 million patient consultations per year). Primary care is provided in family medicine units (FMUs) where GPs are the gatekeepers for specialist care. There are 1109 FMUs distributed through all 32 counties in Mexico (IMSS 2011). FMUs have from 1 to 40 consultation rooms and from 2 to 80 GPs, working in morning or afternoon sessions. Each GP provides healthcare to around 2400 people. The basic service in FMUs is medical care. Larger FMUs (more than four consultation rooms) might provide additional services such as:

- preventive medicine (e.g. vaccinations and screening services)
- laboratory tests
- X-rays
- pharmacy
- social services (provided by social workers, e.g. health education)
- dental services
- occupational health
- nutrition
- psychology
- health promotion (e.g. maternal and child care)
- family planning
- emergency services (available 24 hours a day, seven days a week).

Family medicine units are equivalent to the general practices of the United Kingdom. However, all staff and health services in MISS, including medical care, are based at the same facility, and patients are registered to a GP who provides care to a predetermined catchment area meaning that they cannot choose their GP.

The model of primary care in MISS is part of 'extended general practice'. In this model, GPs are the referral point and the gatekeepers for secondary and social care (Meads 2006).

The next section provides a general description of the UK health system to set the context for a comparison between UK and Mexican primary care system, as this level is the focus of the Thesis. The comparison will also be focused on primary care at MISS because this institution is the place of data collection for the Thesis and there are

differences between Mexican providers (Ministry of Health, Social Security institutions and private services).

3.6 United Kingdom health system

Health services in the UK are mainly provided by the National Health Service (NHS), and include preventive medicine, primary care and hospital services. The NHS is financed by public sources (primarily general taxation and national insurance contributions). All settled residents at the UK receive health services free at the point of use. There are also private services by voluntary health insurance schemes covering around 13% of the population (Boyle 2011).

3.7 United Kingdom and Mexican primary care systems

A review of the UK health system included five aspects of primary care services (Boyle 2011) which are also included in the comparison between UK and Mexico (Table 3.2).

The provision of primary care services takes place in more than one organisation in the UK and most Family Medicine Units provide all primary care services at the same facility in Mexico. The number of primary care services provided in FMUs depends on the size of the unit, and smaller FMUs are usually rural. Patients attend hospitals to receive complementary care when FMUs do not provide them (i.e. laboratory tests).

The key role of GPs in the UK is as team leaders, but primary care is not provided by teams in Mexico. GPs are the first point of contact and gatekeepers to secondary and specialist care in both UK and Mexico. In the UK, patients can choose a GP but they might be seen by other GPs who are available at the practice when patients attend the practice. Patients in Mexico are usually seen by the same GP and it is more likely that they receive more continuity of care.

The average consultation time is 15 minutes in general practice at MISS regardless of the presenting problem of the patient (IMSS 2006). In terms of wider literature, the average consultation is 10 minutes in Europe ranging from 7 (Germany) to 15 minutes (Switzerland) (Deveugele et al. 2002).

There is no published information about what happens during a consultation for a patient with type 2 diabetes at MISS. Informal discussions with 5 clinical colleagues at MISS confirmed that, according to MISS protocols, 15 minutes is the time that they should spend with every patient, although one of the respondents said that more time is spent with some patients if clinically necessary. For example, the standard time of 15 minutes may not be enough when providing care to a patient for the first time, when it is necessary to do a comprehensive evaluation including medical history, physical examination, blood tests (referral to a laboratory), medical prescription (patients usually have more than one condition and therefore more medications), explanation about prescribed medications and recommendations for lifestyle changes (e.g. diet and exercise).

In the standard 15 minute consultation, GPs ask patients with diabetes about hyperglycaemic symptoms (thirst, hunger and frequent urination), current medications, and recent blood tests. GPs also examine patients' eyes, feet, heart, lungs and blood pressure. It is usual that patients have at least one other condition or presenting complaint when they attend the practice. GPs provide a medical prescription (if necessary) based on history-taking and exploration. The medical prescription can be just a repeat prescription or the prescription can change (e.g. more or less oral low-glucose medications based on glucose levels from blood tests). GPs also explain how to take the medications and they give recommendations about exercise and diet. Patients can be referred to other services or secondary care by the GP (e.g. health education, nutritional advice, or consultation with an ophthalmologist). The GP respondents stated that the main aims of the monthly consultation at MISS are to check metabolic control and to provide prescription slips. This can leave little time for doing things other than routine processes.

Health education is organised by social workers at MISS. Health education is provided to group of patients and the sessions are usually led by social workers but sometimes other health professionals are invited to give talks (e.g. nutritionists and general practitioners). The sessions include the following information (Arcega-Dominguez and Celada-Ramirez 2008), p. 687:

a) Basic information about diabetes (epidemiology, definition, anatomy, physiology).

b) Acute and chronic complications (retinopathy, nephropathy, neuropathy, heart attack, stroke, peripheral vascular disease).

c) Treatment (diet, exercise, oral low-glucose medications, and insulin).

d) Self-monitoring.

e) Family support.

Gonzalez-Zuñiga and Andrade-Islas (2000) reported that 33% of patients with diabetes at MISS attend health education, although without providing empirical evidence for this.

Primary care is provided in a different manner by UK and Mexico. This difference can affect the management of diabetes. For example, self-management support is not usually provided by GPs in Mexico. Therefore, the main research questions in this Thesis (*RQ3, RQ4, RQ5, and RQ6,* included on pages 19 and 20) would be answered differently if they were studied in a different context such as the UK.

Table 3.2 United Kingdom and Mexican primary care systems

Primary care	United Kingdom	Mexico
Organisations to provide primary care	GP practices NHS Direct NHS walk-in centres Dentists Opticians Pharmacist	Family medicine units
Key primary care providers	GPs Nurses (practice nurses and district nurses) Midwives Health visitors Physiotherapists Chiropodists Occupational therapists Counsellors Speech therapists Administrative staff	GPs Receptionist per GP Nurses Social workers Nutritionists Dentists Laboratory staff X-ray staff Administrative staff
Access to primary care services	GPs are the first point of contact and gatekeepers to secondary and specialist care	GPs are the first point of contact and gatekeepers to secondary and specialist care
Choice of GP	Patients can choose a GP as their assigned GP	Patients are registered to a GP in a specific catchment area
Average GP list of registered patients	1423	2400

3.8 Summary

National life expectancy at birth in Mexico (75 years) is higher than the average of upper-middle-income countries (72 years). The national prevalence of main long-term conditions and risk factors in adults is 7% for diabetes, 15% for hypertension, and 8% for hypercholesterolemia, with rates of patients who are overweight or obesity at 70%. The Mexican healthcare system is run by the Ministry of Health, social security institutions, and private services. The WHO measured health system performance of 191 countries in the year 2000, with Mexico performing similarly to a mix of upper-middle-income, low-middle-income, and high-income countries. MISS is the biggest social security institution in Mexico and the place of data collection for this Thesis.

There are some similarities between UK and Mexican primary care systems, such as the key role of GPs as gatekeepers of secondary and specialist care but there are some differences as well. These differences can influence the way that primary care is provided. Patients are usually seen by the same GP in Mexico but GPs provide care in consultations lasting only 15 minutes. This time is restricted to provide diagnostic and curative care without the opportunity to provide other services such as self-management support. However, some GPs can do more in order to meet needs of the patient.

Chapter 4
Diabetes

4.1 Introduction

This chapter focuses on diabetes. Although there is more than one type of diabetes, I focus on type 2 diabetes, and this chapter provides a definition and a description of its management and common comorbidities.

Three research questions in this Thesis are focused on glycaemic control and its related factors: *RQ4, RQ5, and RQ6* (included on page 20).

This chapter addresses issues related to these research questions and included in Box 4.1. These issues set the basis to understand what the management of type 2 diabetes includes (i.e. self-management and oral antidiabetic medications) and that following the guidelines and recommendations can diminish diabetes burden through glycaemic control. Diabetes is the leading cause of death in Mexico, and so it is a policy and health priority to diminish its burden.

Box 4.1 Key points from Chapter 4

- Diabetes is defined based on diagnostic criteria of raised blood glucose and the ICD-10 code 'E11 non-insulin dependent diabetes mellitus'
- Diabetes is a condition with global burden because of its prevalence, mortality and costs
- This burden can be diminished with healthy lifestyle choices and guideline recommended glycaemic control
- Target levels of glycaemic control vary
- Management of type 2 diabetes includes self-management, oral antidiabetic medications and insulin therapy
- Patients with diabetes usually have more than one comorbid condition

4.2 Definition of diabetes

Diabetes occurs when there is a lack of insulin or a resistance to its action, leading to raised blood glucose (Joint Formulary Committee 2011; WHO 2011b). The WHO and the International Diabetes Federation recommend at least one of two criteria to diagnose diabetes (WHO and IDF 2006):

> Fasting plasma glucose ≥7.0 mmol/l (126 mg/dl)
>
> 2-h plasma glucose ≥11.1 mmol/l (200 mg/dl) after ingestion of 75g oral glucose load

The International Classification of Diseases-10 classifies diabetes among the endocrine, nutritional, and metabolic diseases, giving the codes E10–E14 diabetes mellitus (WHO 2012a). I focus on type 2 diabetes classified as E11 non-insulin dependent diabetes mellitus.

This Thesis is about adult people with diagnosed diabetes and it is not about the process of diagnosis (Summerton 2011).

4.3 Global burden of diabetes

The International Diabetes Federation (IDF) estimates that 552 million adults will have diabetes in 2030 (IDF 2011d). Although data for 2012 is not available, the trend of global diabetes prevalence is upward with an estimate of 8.3% for 2011 and 9.9% for 2030 (IDF 2011d). This estimate includes both type 1 and type 2 diabetes, but type 2 diabetes accounts for 90% of all cases of diabetes (IDF 2011e). Mexico is among the ten countries with the highest number of people with diabetes (estimated at 10.3 million for 2011 and predicted to reach 16.4 million by 2030) (IDF 2011d).

There are complications associated with poor glycaemic control in people with diabetes, such as retinopathy (damage to the retina), nephropathy (kidney failure), and neuropathy (damage to the nerves) (WHO 2011b). The estimate of mortality related to diabetes in 2011 is 4.6 million worldwide (IDF 2011d). The global economic burden of

treatment and prevention of diabetes and its complications is estimated to be at least US$465 billion for 2011 (IDF 2011b).

Complications and premature mortality can be minimised by interventions to keep glycaemic control under target levels as stipulated in clinical guidelines (UKPDS 1998a; UKPDS 1998b). Glycated haemoglobin measures blood glucose levels over the previous 2 or 3 months (Diabetes UK 2011) and has been recommended as a measure of glycaemic control (IDF 2011a). However, target levels vary (Box 4.2) and there has been recent debate about target levels. For example, Lehman and Krumholz (2009) commented on recent trials that reducing HbA1c <7% in adults >60 years old and having had diabetes for over 8 years increased the risk of hypoglycaemia and mortality (Lehman and Krumholz 2009). There is not a consensus definition of hypoglycaemia based on blood glucose levels (Cryer 2009; Frier 2009; Graveling and Frier 2009). Amiel et al. (2008) identified definitions of hypoglycaemia ranging from 55 to 70 mg/dl (Amiel et al. 2008). The American Diabetes Association (ADA 2013) suggested that blood glucose <70 mg/dl should be considered as hypoglycaemia. This blood glucose cut-off value would prevent clinically important hypoglycaemia (Cryer 2009). Therefore, I define hypoglycaemia as blood glucose levels <70 mg/dl.

Less stringent glycaemic control (HbA1c <8%) may be required for patients with a history of severe hypoglycaemia, limited life expectancy, diabetic complications, multiple comorbidities, and long-standing diabetes (ADA 2013). The debate about HbA1c target levels has raised proposals to update clinical guidelines. For example, there is a review of the clinical guidelines for the management of type 2 diabetes by the National Institute for Health and Clinical Excellence (National Institute for Health and Clinical Excellence 2011), and the appropriate HbA1c target was an additional area to consider for review. In 2012, the American Diabetes Association and the European Association for the Study of Diabetes developed evidence-based recommendations for the management of hyperglycaemia in adults with type 2 diabetes (Inzucchi et al. 2012). These recommendations include HbA1c targets for most adult patients with type 2 diabetes (HbA1c <7%); more stringent HbA1c targets (HbA1c 6.0–6.5%) for selected patients who have been newly diagnosed or who have diagnosed for less than 8 years, long life expectancy, no significant cardiovascular conditions, and without adverse effects of treatment like hypoglycaemia, and less stringent HbA1c targets (HbA1c 7.5–8.0%) for patients with specific characteristics such as a history of severe

hypoglycaemia, limited life expectancy, complications and comorbid conditions (Inzucchi et al. 2012).

Diabetes or glucose control refers to HbA1c <7% as recommended by the MISS diabetes practice guideline (IMSS 2012) to evaluate whether GPs should increase medications to achieve glucose control in this Thesis. Including patients 40 years and older with or without complications and comorbidities makes it more appropriate to use HbA1c levels as the outcome in this Thesis, according to Lehman and Krumholz (2009), who comment about reducing HbA1c <7% in adults >60 years old and having diabetes for over 8 years. Therefore, the outcome in this Thesis is HbA1c levels as continuous variable and referred as glycaemic control in the research questions.

Box 4.2 Target levels for glycaemic control

- National Institute for Health and Clinical Excellence = HbA1c 6.5% (National Collaborating Centre for Chronic Conditions 2008)
- American Diabetes Association = HbA1c <7% (ADA 2013)
- Mexican Ministry of health = HbA1c <6.5% (Secretaria de Salud 2008)
- Mexican Institute of Social Security = HbA1c <7% (IMSS 2012)

4.4 Management of type 2 diabetes

Patients with diabetes are recommended to manage their condition with diet, exercise (i.e. see self-management in diabetes, Chapter 5), education, oral antidiabetic medications, insulin, and usually a combination of these approaches (ADA 2013; IMSS 2012; National Collaborating Centre for Chronic Conditions 2008; Secretaria de Salud 2008). Although every clinical practice guideline includes recommendations about diet, exercise, and education, these recommendations can be general or specific. For example, the clinical practice guideline from the Mexican Ministry of Health just mentions that diabetes treatment includes diet, education, exercise, and self-monitoring (Secretaria de Salud 2008). Other guidelines, for example, are more specific including the components of a healthy diet plan (ADA 2013; IMSS 2012; National Collaborating Centre for Chronic Conditions 2008). Every clinical practice guideline includes diabetes education focusing on self-management support (ADA 2013; IMSS 2012; National

Collaborating Centre for Chronic Conditions 2008). These guidelines highlight that patients should take an active role in the management of diabetes. This active role means that patients make decisions together with health professionals about what diet, exercise, education, and medications are best to control diabetes, based on their needs and preferences. Although health professionals can make recommendations for diabetes management, patients are the managers of their condition. Therefore, good diabetes management and control is as much the responsibility of the patient as it is to medical care according to these practice guidelines.

The sixth research question in this Thesis is related to this issue of shared diabetes management (included on page 20).

The following paragraphs describe recommended insulin and antidiabetic medications for the treatment of diabetes by the British National Formulary (BNF) and Martindale. (Martindale 2011) Diabetes treatment is based on the aim of maintaining glucose control via gradually intensified treatment because diabetes will deteriorate over time for most patients. Therefore, insulin will be prescribed after attempting control with other methods (i.e. diet, exercise, and oral diabetic medications) without achieving appropriate control (Joint Formulary Committee 2011). Insulin 'inhibits hepatic glucose production and enhances peripheral glucose disposal thereby reducing blood-glucose concentration' (Martindale 2011). There are three types of insulin: short-acting (onset within 30 to 60 minutes and duration up to 8 hours), intermediate-acting (onset after about 2 hours and duration up to 24 hours), and long-acting (onset after about 4 hours and duration up to 36 hours) (Martindale 2011). The BNF recommends three types of oral antidiabetic medications: sulphonylureas, biguanides, and other antidiabetic medications (Table 4.1).

Even in patients with type 2 diabetes who take medication and have healthy lifestyles, blood glucose levels increase over time (Drury and Gatling 2005). This increase in blood glucose levels and the risk of hypoglycaemia in patients under tight control make diabetes a complex condition in terms of medical treatment.

Table 4.1 Antidiabetic medications: action and availability

Antidiabetic medication	Action
Sulphonylureas Glibenclamide Glicazide Glimepiride Glipizide Tolbutamide	'The sulfonylureas act mainly on augmenting insulin secretion and consequently are effective only when some residual pancreatic beta-cell activity is present'. It is recommended in patients who have normal weight or contraindication or intolerance to metformin.
Biguanides Metformin	Metformin 'exerts its effect mainly by decreasing gluconeogenesis and by increasing peripheral utilisation of glucose, since it acts only in the presence of endogenous insulin it is effective only if there are some residual functioning pancreatic islet cells'. Metformin is recommended in patients who are overweight.
Other antidiabetic drugs Acarbose	Acarbose is an 'inhibitor of intestinal alpha glucosidases' that 'delays the ingestion and absorption of starch and sucrose; it has a small but significant effect in lowering blood glucose'. Acarbose is recommended when other antidiabetic medications have not worked in obtaining control.
Nateglinide and repaglinide	'Nateglinide and repaglinide stimulate insulin release.' Repaglinide is recommended in patients who have normal weight or contraindication or intolerance to metformin. Nateglinide should be used with metformin.
Pioglitazone	Pioglitazone is a thiazolidinedione that 'reduces of peripheral insulin resistance and leads to a reduction of blood-glucose concentration'. Pioglitazone is recommended to use alone or in combination (with metformin or sulfonylurea).
Saxagliptin, sitagliptin, and vildagliptin	'Saxagliptin, sitagliptin, and vildagliptin inhibits of dipeptidylpeptidase-4 increases insulin secretion and lower glucagon secretion.' These are recommended to use in combination with metformin, sulfonylurea or pioglitazone. Sitagliptin is recommended to use alone or in combination with insulin.
Exenatide and liraglutide	'Exenatide and liraglutide both bind to, and activate, the GLP-1 (glucagon-like peptide-1) receptor to increase insulin secretion, suppress glucagon secretion, and slow gastric emptying.' These are recommended to use in combination with metformin, sulfonylurea, or pioglitazone.

Source: Joint Formulary Committee 2011.

4.5 Comorbidity in diabetes

When people have more than one recorded clinical condition, these conditions are known as comorbidities (Fried et al. 2004). Comorbidity in diabetes can have an impact on the care that patients receive both for diabetes and for the comorbid condition (Ritchie 2007; Valderas et al. 2009) and for their self-management (Piette and Kerr 2006). For example, some comorbid conditions in patients with diabetes can be more complex or serious and can supersede medical management of diabetes (e.g. cancer). Other conditions can be disabling (e.g. dementia) and affect self-management behaviours (e.g. healthy eating and physical activity). Prevalence of comorbid conditions in diabetes vary. For example, 17.6% of patients with diabetes can also have depression (Ali et al. 2006), 40% hypertension (Mobashir et al. 2005), and 50% obesity (Dixon 2009).

Depression has been related to decreased self-management and quality of care in previous studies (Ciechanowski et al. 2000; Egede et al. 2009; Egede and Osborn 2010; Gonzalez et al. 2007; Gonzalez et al. 2008). Patients with diabetes and depression are less likely to follow a diet or to take diabetes medications (Egede et al. 2009; Gonzalez et al. 2007). Quality of care also decreases in patients with diabetes and depression because these patients are less likely to receive diabetes care as recommended by practice guidelines (i.e. eye examinations) (Egede et al. 2009).

I evaluate comorbid conditions in the participants as covariates including depression, hypertension, obesity and other conditions (see Appendix 8.4, section 'I.5 Comorbidity', p. 325-326). Comorbid conditions were part of the clinical factors included in three research questions of this Thesis: *RQ2, RQ4, and RQ5* (see pages 19 and 20).

4.6 Summary

Diabetes is defined based on diagnostic criteria and is a condition with a global burden because of its prevalence, mortality, and costs. It has been suggested that the diabetes burden can be diminished by controlling glucose levels. Target glucose levels can vary for individual patients. Target levels of HbA1c of 6.0–6.5% are recommended for patients who have short diabetes duration, long life expectancy, no significant

cardiovascular conditions, and are without adverse effects of treatment like hypoglycaemia. Less stringent HbA1c targets (7.5–8.0%) are recommended for patients with a history of severe hypoglycaemia, limited life expectancy, complications, and comorbid conditions.

The management of type 2 diabetes is broad and complex, including diet, exercise, education, oral antidiabetic medications, and insulin. Good diabetes management and control depend on both patient characteristics and self-management behaviours and good quality medical care. Comorbid conditions such as depression, hypertension, and obesity are common in patients with diabetes.

Mexico is one of the ten countries with the highest number of people with diabetes, and type 2 diabetes accounts for 90% of all cases of diabetes. I focus on type 2 diabetes after diagnosis studying factors that are related to glucose control. These factors are related to patients (self-management) and medical care (quality of care) because both patients and medical care contribute to glucose control. For example, patients who manage their condition are more likely to follow a healthy diet and take prescribed medications. An example of quality of care is when health professionals intensify medical treatment (increasing medications or dose) to achieve target or improved HbA1c levels. Comorbid conditions can affect self-management and quality of care. Therefore, the analyses reported in this Thesis controls for the presence of comorbid conditions.

Chapter 5 summarises and critiques the evidence base for self-management and quality of care and specifies and justifies the respective aspects to be used in this Thesis.

Chapter 5
Self-management and quality of care

5.1 Introduction

This chapter explores the concepts of self-management and quality of care in relation to diabetes and establishes the conceptual definitions that will be used in the Thesis. This chapter provides a framework to address the first research question in this Thesis (included on page 19).

This chapter also explores self-management and quality of care in the Mexican healthcare context, which was outlined in earlier chapters. The Mexican studies of self-management and quality of care do not answer the main research question in this Thesis (*RQ6,* included on page 20).

Box 5.1 Key points from Chapter 5

- The terms self-management, self-care and self-help are often used inter-changeably
- Self-management is focused on the management of long-term conditions such as diabetes
- Self-management in diabetes includes physical activity, achieving a healthy weight, healthy eating, avoidance of tobacco, monitoring of the condition, coping with emotional impacts, and taking medications
- Self-efficacy and knowledge are suggested as core determinants of self-management
- I will focus on three aspects of self-management: behaviours, self-efficacy, and knowledge
- Quality of care is a complex concept without an agreed definition and it includes different domains and dimensions
- I will focus on three dimensions of quality of care: continuity of care, clinical care, and interpersonal care

5.2 Self-management

The concepts of self-management, self-care, and self-help are often used interchangeably without a clear distinction between them. Box 5.2 includes definitions proposed by a range of authors.

Box 5.2 Definitions of self-care, self-help, and self-management

Self-care is a process whereby a layperson can function effectively on his own behalf in health promotion and prevention and in disease detection and treatment at the level of the primary health resource in the healthcare system (Levin 1976, p. 206).

Self-care refers to the practices of individuals and families through which the forms or symptoms of illness are detected and treated, other diseases are prevented, and positive health behaviour is generally promoted (DeFriese et al. 1989, p.195).

Self-care is learned, goal-oriented activity of individuals. It is behaviour that exists in concrete life situations directed by persons to self or to the environment to regulate factors that affect their own development and functioning in the interest of life, health, or well-being (Orem 1991, p. 64).

Self-care is response behaviour to a perceived symptom without the involvement of physicians (Haug et al. 1991, p. 1011).

Self-care includes the actions that people take for themselves, their children and their families to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; care for minor ailments and long-term conditions; and maintain health and well-being after an acute illness or discharge from hospital (Department of Health 2005, p. 1).

Self-care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a healthcare provider (WHO & SEARO 2009, p. 17).

Self-help was defined as a therapeutic intervention of self-treatment administered through group meetings mainly independent of professionals (den Boer et al. 2004, p. 961).

Self-help refers to treatments without any therapist contact (Gellatly et al. 2007, p. 1217).

Self-management refers to the performance of preventive or therapeutic healthcare activities, often in collaboration with healthcare professionals (Tobin et al. 1986, p.29).

Self-management is the day-to-day tasks an individual must undertake to control or reduce the impact of disease on physical health status. At-home management tasks and strategies are undertaken with the collaboration and guidance of the individual's physician and other healthcare providers (Clark et al. 1991, p. 5).

Self-management refers to the individual's ability to manage the symptoms, treatment, physical, and psychosocial consequences and life style changes

inherent in living with a chronic condition (Barlow et al. 2002, p. 178).

Self-management is patient's mastery of three technical skills of chronic conditions: medical, social and emotional (Bodenheimer et al. 2002, p. 2472).

Self-management is day to day management of three tasks (medical or behavioural, life roles, and emotional) and five skills (problem-solving, decision making, resource utilisation, forming of a patient/healthcare provider partnership, and taking action) (Lorig and Holman 2003).

Self-management is defined as the tasks that individuals must undertake to live well with one or more chronic conditions. These tasks include having the confidence to deal with medical management, role management, and emotional management of their conditions (Committee on the Crossing the Quality Chasm: Next Steps Toward 2004, p. 57).

Self-management consists of the patient's daily effort to cope with the symptoms, treatment, physical, and social consequences, and lifestyle changes inherent to living with a chronic condition (Nuovo et al. 2007, p. 226).

Self-management refers to those tasks that individuals undertake to deal with the medical, role, and emotional management of their health condition(s) (McCorkle et al. 2011, p. 51).

These definitions vary in several ways. Existing self-management definitions focus on long-term conditions (Barlow et al. 2002; Bodenheimer et al. 2002; Committee on the Crossing the Quality Chasm: Next Steps Toward 2004; Nuovo et al. 2007), whereas self-care definitions include prevention and therefore are relevant to healthy people as well as people with long-term conditions. I focus on diabetes as a long-term condition which makes it more appropriate to use the term of self-management.

Definitions also vary in their inclusion of the healthcare professional. Collaboration of healthcare professionals is included in some self-management definitions (Tobin et al. 1986; Clark et al. 1991) but most self-care definitions do not specify this collaboration or even leave open the option of support from healthcare professionals, because of the focus on self-care as a way of reducing the burden on health systems (WHO & SEARO 2009). Self-care is also relevant to healthy people who might not need support from healthcare professionals. Although professional input can differentiate between self-care and self-management, there is not a clear consensus about this distinction. For example, health professionals are part of the support for self-care in people with long-term

conditions (Rogers et al. 2011). I include patients with diabetes under the care of GPs. The definition adopted must have the potential for both patient management of the condition and support from healthcare professionals because diabetes management almost always involves medical treatment prescribed and supervised by GPs.

The scope of these definitions also varies in terms of their focus. Some self-management definitions are focused on specific tasks or skills, for example, the management of the condition by taking medications or following a healthy diet (Bodenheimer et al. 2002; Lorig and Holman 2003; Committee on the Crossing the Quality of Chasm: Next Steps Toward 2004; McCorkle et al. 2011). Definitions also vary in terms of the problems that self-management is designed to address. Some definitions focus on medical issues (such as the 'disease detection and treatment' in Levin 1976), while many others include emotional and social issues. For example, the United Kingdom Department of Health proposes a broad definition of self-care including physical, mental, social, and psychological aspects. Patients with long-term conditions are not only affected in terms of physical health but also in their social, psychological and mental health. For example, depression (see Chapter 4) is more frequent in patients with long-term conditions (Egede 2007) and it is related to self-management (Bayliss et al. 2007; Jerant et al. 2005).

Some definitions of self-care include family and community as part of self-management (DeFriese et al. 1989; Department of Health 2005; WHO & SEARO 2009). Family and communities as well as friends are part of the social support networks that patients with long-term conditions often receive. However, social support seems to have both positive and negative effects on self-management (Gallant 2003). For example, positive social support would include supportive spouses who help patients with dietary changes. Negative social support would include the 'unwillingness of family members to adjust their own diet' (Gallant 2003, p. 187). I focus on self-management undertaken by individuals.

Self-management in long-term conditions requires that patients are active participants in medical treatment and responsible for the necessary changes in their daily activities to improve their condition and well-being (Corben and Rosen 2005). Clark et al. (1991) identified 12 common tasks or behaviours in the management long-term conditions. However, the management of individual conditions can be focused on specific activities

to control that particular condition. For example, in chronic heart failure, patients are asked to monitor their blood pressure, weight, and swelling to avoid hospitalisations, as these can signal worsening heart failure (National Clinical Guideline Centre 2010). In diabetes, control is usually focused on glucose levels to prevent diabetes complications. Therefore, 'the essential nature of the task' (Clark et al. 1991, p. 19) is monitoring, but different conditions requires the monitoring of specific signs or symptoms.

To measure self-management in this Thesis, it is necessary to propose an operational definition that makes clear the scope of the term as applied in the Thesis, and describes the specific behaviours that are expected in patients with type 2 diabetes.

5.3 Self-management in diabetes

In Chapter 4, it was mentioned that the management of type 2 diabetes includes diet, exercise, and medications. The current section provides a description about behaviours that patients are advised to perform in the management of their condition and it is expected to happen as a result of good quality clinical care. These behaviours are recommended by clinical guidelines (ADA 2013; IMSS 2012; National Collaborating Centre for Chronic Conditions 2008) and by diabetes organisations (Diabetes UK 2012; IDF 2011c). These behaviours have been included as part of the self-management of long-term conditions (Bodenheimer et al. 2002; Committee on the Crossing the Quality of Chasm: Next Steps Toward 2004).

The aim of diabetes self-management is to control blood glucose, blood pressure, weight, and blood fat levels, preventing diabetes complications in eyes, kidneys, nerves, and the cardiovascular system, as well as limiting the emotional impact of diabetes. Key behaviours in the management of diabetes (Box 5.3) have been defined in the literature (Anderson et al. 2003; Clark 2008; Duke et al. 2009; Heinrich et al. 2010; Naik et al. 2011; Radhakrishnan 2012). However, self-management also includes skills like problem solving, decision making, resource utilisation, forming of an effective patient/healthcare provider partnership, and taking action (Lorig and Holman 2003), which are not part of medically defined behaviours. I will focus on key behaviours that are included in clinical guidelines and it will not include the wider skills suggested by Lorig and Holman (2003). I need to provide a definition of diabetes self-management that can be measured in the routine context of primary care in the Mexican context. In

Mexico, diabetes self-management programmes are focused on medically defined behaviours and delivered by healthcare professionals as recommended by Mexican practice guidelines. Wider skills such as those suggested by Lorig and Holman (2003) are generally acquired in self-management programmes which are not available in Mexico.

On the basis of a synthesis of the definitions in Box 5.3, and considerations of the context of the current research, the proposed definition of diabetes self-management is as follows:

> *Patients' performance of key behaviours in collaboration with their healthcare provider: physical activity, healthy eating, avoiding tobacco, monitoring diabetes control, and taking prescribed medications.*

The proposed definition includes the management of physical aspects of diabetes, and involves collaboration with healthcare professionals. Although the prevention of complications is part of diabetes management, this definition does not include the prevention of other conditions. Finally, the focus is on individuals; therefore, family and community are not included in this definition.

Chapter 8 describes the methodology that was used to measure diabetes self-management in this Thesis using validated questionnaires from interviews with patients.

Box 5.3 Key behaviours in the self-management of diabetes
ADA 2013; Diabetes UK 2012; IDF 2011c

Physical activity: 30 minutes per day, at least 5 days per week

Healthy eating: including variety of foods and reducing consumption of fat and sugar

Avoidance of tobacco or giving up smoking

Monitoring of blood glucose

Taking prescribed diabetes medications: tablets to lower blood glucose levels to keep them under control

5.4 Factors relating to self-management

The previous section has defined the meaning and scope of self-management. The following section will describe factors that may determine the likelihood of self-management being undertaken.

Self-management has been explored from the perspective of social cognition models such as social learning theory (Tobin et al. 1986), social cognitive theory (Clark et al. 1991; Barlow et al. 2002), and self-efficacy theory (Lorig and Holman 2003). Social cognition models propose that factors intrinsic to the individual are predictors of behaviours (Conner and Norman 2005). Among these factors are demographic variables and cognitive factors.

In terms of demographics, the social cognition approach has suggested that 'younger, wealthier, better educated individuals under low levels of stress with high levels of social support are more likely to practise health-enhancing behaviours' (Conner and Norman 2005, p. 3). Two studies have examined which demographic factors are related to self-management behaviours in patients with diabetes in Mexico (Amador-Diaz et al. 2007; Compean-Ortiz et al. 2010).

Amador-Diaz et al. (2007) studied factors related to self-management behaviours in patients with type 2 diabetes (n=200 with diabetes duration between 5 and 15 years and age 40 to 65 years). The factors studied were age, marital status, socioeconomic level, type of housing, type of family, education level, anxiety, depression, fasting blood glucose level, age at diabetes diagnosis, and duration of diabetes. Self-management was measured with a questionnaire developed by Amador-Diaz and colleagues (2007) including seven 'yes-no' questions about diet (two items), medication, exercise, foot care, and help-seeking behaviours (two items). Patients were classified as self-managers when they answered 'yes' to at least five of these questions. Sixty-two per cent of these patients were classified as self-managers, and factors were compared between self-managers and non-self-managers. None of the demographic factors were related to self-management. Fasting blood glucose levels were significantly lower in self-managers than non-self-managers (mean 170.9 SD 61.8 vs. 202.1 SD 80.5, respectively). Patients without anxiety and depression were more likely to be self-managers. However, there was limited information about the validity of the self-management questionnaire

(content validity) and although the study explored various factors, there was no evaluation of their relative importance.

Compean-Ortiz et al. (2010) examined the relationship between self-management behaviours (diet, exercise, monitoring, and medication) and health outcomes (HbA1c, cholesterol, triglycerides, body mass index, waist circumference, and body fat percentage). The study also examined the relationship between age, education level, gender, and diabetes understanding with self-management behaviours and health outcomes. Participants were patients with type 2 diabetes (n=98, age 30 to 55 years). Self-management behaviours were measured with the Spanish version of the Summary of Diabetes Self-Care Activities (Bradley 1994), raw scores were transformed to a 0 to 100 scale (higher score better self-management). Gender was related to self-management exercise behaviours (median of self-management exercise in men 27.7 vs 11.1 in women, $P < 0.01$). Spearman correlations between self-management and health outcomes showed that better self-management in diet was correlated with lower levels of HbA1c, body fat, body mass index, and waist circumference. Better exercise self-management was related to lower cholesterol. Finally, better medication self-management was related to lower triglycerides. In multivariate analysis, diet self-management, gender, and diabetes understanding were significant predictors of health outcomes.

Although Amador-Diaz et al. (2007) and Compean-Ortiz et al. (2010) examined factors related to self-management in Mexican patients with diabetes, the measures of self-management behaviours were different. Amador-Diaz et al. (2007) developed a questionnaire of self-management behaviours without showing information about its validity and reliability but its content validity by general practitioners who agreed about these behaviours as self-management behaviours. Compean-Ortiz et al. (2010) used the same questionnaire to this Thesis but Compean-Ortiz et al. (2010) restricted the sample to younger patients (30 to 55 years old).

I examine demographic factors related to self-management using validated questionnaires to answer the second research question (included on page 19).

Cognitive factors outlined by social cognitive theory include three predictors of health behaviours: situation-outcome expectancy, action-outcome expectancy, and perceived

self-efficacy (Conner and Norman 2005). These refer to individuals' beliefs that outcomes will or will not occur due to external causes (situation-outcome expectancy), due to a given behaviour (action-outcome expectancy), or due to their capacity to perform a specific behaviour (perceived self-efficacy).

There is evidence that self-efficacy is a core variable in self-management. Social cognitive theory has been used to develop self-management interventions, for example the Chronic Disease Self-Management Programmes (CDSMP) (Stanford Patient Education Research Center 2012). Lorig et al. (1984) found that their first programme (the Arthritis Self-Management Course) showed improvements in behaviours and health status in a randomised controlled trial but the authors did not find a correlation between self-management behaviours and health status. Lorig and colleagues examined other mechanisms related to health outcomes in an exploratory study, finding that patients with positive outcomes in health status perceived high levels of self-control over the disease (Lenker et al. 1984). This 'self-control' was explained by the concept of self-efficacy developed by Bandura in 1977 and 1982. Then, Lorig et al. (1989) developed and evaluated a scale to measure perceived self-efficacy, and confirmed the hypothesis of a relationship between perceived self-efficacy and health outcomes (Lorig et al. 1989). Finally, Lorig and colleagues redesigned the self-management programmes, focusing on the improvement of self-efficacy and helping patients to be more confident in the management of their symptoms and in the control of their condition. RCTs using the redesigned CDSMPs found improvements in self-efficacy and health outcomes (Kennedy et al. 2007; Lorig et al. 2008; Lorig et al. 2009; Lorig et al. 2010).

Some studies have examined the efficacy of self-management programmes in long-term conditions based on self-efficacy theory or including the role of self-efficacy in these programmes. A variety of studies were examined in the review by Nunez et al. (2009) including systematic reviews, meta-analysis, intervention studies (RCT and experimental), and a longitudinal design as follow-up to an RCT. They reported that 12 of 16 papers showed improvements in self-efficacy, but they did not measure self-management and therefore there were no data about the relationship between self-efficacy and self-management (Nunez et al. 2009).

Another review examined the role of self-efficacy within five self-management programmes for patients with CVD (Katch and Mead 2010). Self-management was not

measured directly but through outcomes (i.e. lower blood pressure or reduced hospitalisations) reflecting improvement in self-management (i.e. medication adherence or management skills). The first programme was the CDSMP developed by Lorig and colleagues. Although, Katch and Mead (2010) mentioned that the CDSMP programme had been extensively used, the review was focused on one study reported in two papers. The second programme was the Spanish version of the CDSMP. The third programme was the 'Women Take PRIDE'. The acronym PRIDE included the processes of self-regulation: ***P***roblem selecting; ***R***esearching the daily routine; ***I***dentifying a hearth self-management goal; ***D***eveloping a plan to reach the goal; and ***E***stablishing a reward for reaching the goal or making progress (Clark et al. 1992). The fourth programme in the review was focused on the effect of cardiac rehabilitation on exercise self-efficacy. The fifth programme was a disease management programme for low literacy patients with heart failure, focused on the improvement of patients' adherence to disease management and self-efficacy. All programmes showed improvements in self-efficacy and outcomes, but there were no direct self-management measures.

These studies show that self-management programmes improve self-efficacy but there is no evidence about the relationship between self-efficacy and self-management behaviours. This lack of evidence is mainly because the studies did not include direct measures of self-management behaviours. I measure both self-efficacy and self-management behaviours using validated questionnaires and a longitudinal cohort to evaluate relationships between them.

Knowledge is another core variable to self-management. Knowledge is defined from a psychological perspective as 'anything is known' (Colman 2006). This definition includes three types of knowledge: '*declarative knowledge* (knowing that), *procedural knowledge* (knowing how), and *acquaintanceship knowledge* (knowing people, places, and things)' (Colman 2006). It is necessary to know what and how to perform self-management behaviours before patients self-manage their condition. This relationship between knowledge and self-management has been suggested in diabetes self-management education (Funnell et al. 2012). There are reviews including both knowledge and self-management behaviours but these reviews do not measure the relationship between them (Deakin et al. 2005; Duke et al. 2009; Knight et al. 2006; Norris et al. 2001). Few studies have tested whether knowledgeable patients are more likely to perform self-management behaviours (Garrett et al. 2005; Persell et al. 2004).

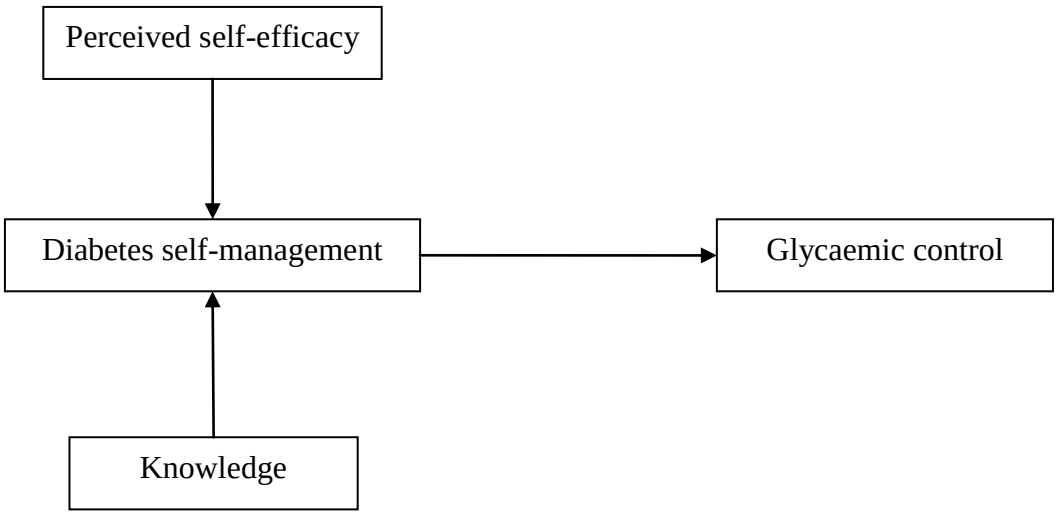
In an observational study including 670 patients with diabetes, a significant relationship was found between diabetes knowledge and self-management behaviours (Persell et al. 2004). However, the study was cross-sectional making it difficult to confirm a causal relationship (i.e. whether diabetes knowledge affects self-management behaviours or vice versa).

Garrett et al. (2005) hypothesised that increased knowledge improves self-management behaviours. This study was an RCT including pre-post comparisons (3 weeks before and after interventions). The intervention was collaborative, including an interactive, small-group learning experience during three months (39 three-hour sessions in total and a self-care book). There were 358 adult patients in the intervention group and 382 patients in the control group (patients received the self-care book). The findings showed that patients in the intervention group increased their knowledge and behaviours more than the control group. The increase in the knowledge index and the behaviour index was higher for the intervention group 1.4 and 1.0 than the control group 0.7 and 0.3, respectively. Although there were increases in both knowledge and behaviours, there was no measure of the relationship between knowledge and behaviours. There was no information about the source of the questionnaires and about their validity. Garret et al. (2005) included the Cronbach's alpha of the indexes (0.85 for knowledge and 0.59 for behaviours).

I evaluate the relationship between diabetes knowledge and self-management behaviours using validated questionnaires in a longitudinal cohort.

Therefore, I propose a diabetes self-management model that includes these two core cognitive factors (self-efficacy and knowledge) in the prediction of glycaemic control (Figure 5.1) and to answer the following research questions: *RQ3, RQ4, and RQ5* (included on pages 19 and 20).

Figure 5.1 Proposed diabetes self-management model



5.5 Self-management in Mexico

Observational studies in Mexico have described diabetes self-management behaviours (Guzman-Perez et al. 2005) and diabetes knowledge (Bustos-Saldaña et al. 2007). Factors related to self-management were included in the previous section of this chapter (Amador-Diaz et al. 2007; Compean Ortiz et al. 2010).

Guzman-Perez et al. (2005) explored self-management behaviours, diabetes knowledge (physiopathology and complications), and glucose control in 69 patients attending diabetes educational sessions. Diabetes knowledge and self-management were explored at the end of the sessions. Fasting blood glucose levels were extracted from medical records at two points (diabetes diagnosis and interview). Half of the patients had good knowledge (51%) and good self-management (49%) but there was no information on how 'good' knowledge and 'good' self-management were defined. Forty patients significantly lowered fasting blood glucose levels at the end of the sessions (mean decrease was 93.8 mg/dL, SD 95.7). Guzman-Perez and colleagues (2005) developed the questionnaires to explore diabetes knowledge and self-management but there is no description of the type of questions, responses, or validation. Knowledge and self-management were classified as good, acceptable, and poor – but again without a description about the classification. Weekly educational sessions lasted for three months, including information about physiopathology, complications, and diabetes control. A multidisciplinary team provided the educational sessions but there was no information about what kind of professionals was part of this team. Fasting blood glucose levels were shown as percentages in the results but these percentages were not statistically compared. The limitations in this study make it difficult to draw conclusions about diabetes knowledge, self-management, and glucose control.

Bustos-Saldaña et al. (2007) compared diabetes knowledge between urban and rural patients with type 2 diabetes in a cross-sectional study (n=988). Diabetes knowledge was measured with the same questionnaire used in this Thesis (Diabetes Knowledge Questionnaire – DKQ-24). Total score of DKQ-24 ranges from 0 to 24 (Garcia et al. 2001). Mean total score of DKQ-24 was significantly higher in urban than in rural patients (12.6 SD 3.2 vs. 13.6 SD 3.2, respectively). It was expected that rural patients would have higher diabetes knowledge because they were recruited from a diabetes

programme which includes education about diabetes, but the paper does not specify what kind of diabetes information patients had received.

There is no single 'self-management programme' in the Mexican health context but other programmes, for example, diabetes self-help groups (Hernandez-Leyva et al. 2005; Lara-Esqueda et al. 2004; Velazquez-Monroy et al. 2001), include diabetes knowledge and self-management behaviours that were described in section 5.3 in this chapter (e.g. healthy eating and physical activity). Although, these groups are called 'self-help groups', they are supervised by health professionals, and the focus is on health education. An observational study evaluated the impact of these groups showing that fasting blood glucose (FBG) levels decreased from 222 mg/dl at baseline to 140 mg/dl at follow-up (4 months after the end of the group) (Lopez-Portillo et al. 2007). The design limitations of this study (observational without any control of the intervention) make us less confident that the effects are caused by the group but the study did demonstrate quite significant effects for a short treatment (a month including six sessions). However, there was no multivariate analysis controlling for confounders, therefore, it is not possible to know whether the effect was purely caused by this intervention.

Previous studies of self-management in the Mexican context have not used validate measures of self-management behaviours and diabetes knowledge (Guzman-Perez et al. 2005; Amador-Diaz et al. 2007) and there was no published evidence about studies of self-efficacy in patients with diabetes. I will use validated measures of self-management behaviours and diabetes knowledge as well as a measure of diabetes self-efficacy.

Compean-Ortiz et al. (2010) used a validated measure of self-management behaviours and explored various factors of HbA1c but there was no evaluation of the relative importance of these factors to glycaemic control. My aim is to evaluate the relative importance of self-management (behaviours, knowledge, and self-efficacy) and quality of care as factors of glycaemic control in patients with type 2 diabetes.

Box 5.4 Summary of self-management evidence

- There is no published evidence of studies in Mexico measuring the role of self-efficacy, despite the fact that it is clearly important in the wider literature
- I will include a measure of self-efficacy as part of diabetes self-management
- Previous Mexican studies of self-management have had some limitations such as the lack of validated questionnaires and the lack of evaluation of the relative importance of factors related to glycaemic control
- I will use validated measures of self-management and will evaluate the relative importance of these factors to glycaemic control

5.6 Quality of care

The aim of this section is to define quality of care in the context of primary care. To achieve this aim, the section starts by describing the health system, because good primary care has been suggested to be part of an integrated health system (World Health Organization 2004). This description is followed by concepts and definitions of primary care and the role of GPs. The final sections are about definitions, dimensions, and measures of quality of care.

5.6.1 Health system

Authors have referred to different functions, components, types, and levels of healthcare systems (Field 1989; Londono and Frenk 1997; Mills and Ranson 2006; Plochg and Klazinga 2002; Roemer 1993; WHO 2000) but healthcare systems consist of similar components (facilities, equipment, staff, organisation, programmes, fiscal organisation, etc.) (Donabedian 1966; Donabedian 1980). Health systems are all context specific and the product of historical, social, cultural, economic, demographic, and political influences which have determined how every healthcare system has evolved. So the way they are organised, financed, and staffed will differ according to that context.

As the 2007 WHO report *Everybody's Business* states: 'A health system consists of all organisations, people, and actions whose *primary intent* is to promote, restore, or

maintain health' (WHO 2007, p. 2). It has been suggested that health systems have different tiers or levels (micro-meso-macro) (Plochg and Klazinga 2002). This separation of levels may prevent the development of integrated health systems because this integration is expected to be driven by the 'principles of primary healthcare and related policies in order to progress towards the goal of improving population health' (WHO 2004, p. 3).

The role and prominence that primary care plays in a country's system, and how well it is integrated within that system, will, and does, also vary (Roemer 1993; Starfield et al. 2005; WHO 2008). In Mexico, primary care delivers approximately 85% of all health services in MISS (Ruiz-Hernandez et al. 2005). Evidence suggests that countries with effective primary care systems have better health outcomes (e.g. prevention of illness and death) (Macinko et al. 2007; Macinko et al. 2009; Shi et al. 2003a; Shi et al. 2003b; Shi et al. 2004; Shi et al. 2005a; Shi et al. 2005b; Shi et al. 2005c; Starfield et al. 2005).

I focus on quality of primary care and this perspective includes not just the provision of care from providers but also the participation of patients to potentially achieve desired outcomes; in this case, diabetes control. The following sections define and describe primary (health) care.

5.6.2 Primary care

The terms 'primary healthcare', 'primary care', 'family medicine', 'general practice' and 'family practice' have often been used interchangeably but some authors have proposed specific definitions for each of these terms.

Primary healthcare was defined by the WHO, from a perspective of health systems:

'The development of health systems needs to be driven by the principles of primary healthcare and related policies in order to progress towards the goal of improving population health. Thus the capacity of the health system to deliver accessible care to all becomes more important than primary care as a specific level. This means that effective primary care must operate close to the community it serves, but does not have to be seen as a separate and distinct level of care. Therefore enabling co-ordinated, patient-centred care across the continuum of prevention and care requires the

development of integrated health systems that are led by primary healthcare yet blur the conventional distinctions between levels of care' (WHO 2004, p. 3).

Greenhalgh (2007) defines 'primary healthcare' by focusing on the provision of services from the perspectives of patients and health professionals:

'Primary healthcare is what happens when someone who is ill (or who thinks he or she is ill or who wants to avoid getting ill) consults a health professional in a community setting for advice, tests, treatment or referral to specialist care. Such care should be holistic, balanced, personalised, rigorous and equitable, and delivered by reflexive practitioners who recognise their own limitations and draw appropriately on the strengths of others' (Greenhalgh 2007, p. 12).

Starfield (1998) used the term 'primary care' referring to primary medical care and suggests that primary care has unique features that differentiate it from other health services (e.g. specialist care): first contact, longitudinality, comprehensiveness, and coordination (Box 5.5). The inclusion and definition of features of primary care makes this a more comprehensive perspective which will be used in this Thesis. The aspects of quality of care included in the research questions are focused on the context of primary care in Mexico characterised by first contact and longitudinality with a GP.

Box 5.5 Features of primary care

1. First contact (primary care as gatekeeper to the health system)
2. Coordination (primary care providers coordinate the use of other health services)
3. Comprehensive care (inclusion of preventive, curative, and rehabilitative care)
4. Longitudinality (care is focused on patients over time by a primary care team)
5. Family and/or community orientation (patients are treated taking into account their familial and social context)

(Macinko et al. 2003; Starfield 1998)

General practice and family medicine have also been used as synonyms for primary care but these terms have been defined as 'an academic and scientific discipline, with its own educational context, research, evidence base and clinical activity and a clinical specialty orientated to primary care' (WONCA Europe 2011, p. 8). WONCA also defines GPs or

family doctors as ‘specialist physicians trained in the principles of the discipline’ (WONCA Europe 2011, p. 8).

I will use the term ‘primary care’ based on the definition of Starfield (1998) and Macinko et al. (2003). Starfield (1998) specified that primary care in the USA referred to family medicine (as a speciality) which is embodied in the broader term of primary care. Although family medicine/practice/practitioner is the more frequently used term (in USA, Canada, Mexico, and much of Europe), the term GP will be used in this Thesis as a shorthand for both general and family practitioner.

GPs have different roles depending on their organisational and health system context (Meads 2006) but they may or may not (in most of Continental Europe) be the referral point and the gatekeeper for secondary and social care as well as the team leader in a team-based care in a context of primary care (Macinko et al. 2003; Meads 2006; Starfield 1998). This role of GPs has been included in a model of primary care called ‘extended general practice’ (Meads 2006). However, these models might not be automatically transferable between different healthcare systems because every system has unique characteristics. For example, in Mexico, MISS provides primary care including different providers (GPs, nurses, dieticians, etc.) where GPs are the referral point and gatekeepers but they do not lead a primary healthcare team because these health professionals do not work in teams (see Chapter 3). Reimbursement to GPs also differs between organisations. Three types of payment for GPs have been suggested: fee for service (reimbursement by service or procedure), salary (fixed compensation), and capitation (fixed payment by number of assigned patients) (Starfield 1998). GPs in MISS received a salary. Therefore, patients do not need to pay at point of contact making it more accessible to receive health services in this institution (see Chapter 3).

5.6.3 Definitions and domains of quality of care

There is no agreed or unique definition of quality of care (Greenhalgh 2007; Raleigh and Foot 2010) but Box 5.6 shows some definitions.

Box 5.6 Definitions of quality of care

Quality of care has two domains: technical and interpersonal care. *Technical care* is the application of the science and technology of medicine, and of the other health sciences, to the management of a personal health problem. *Interpersonal care* is the management of the social and psychological interaction between client and practitioner (Donabedian 1980, p. 4). These domains are proposed to be a set of activities called 'process of care' which take place within specific structures or settings of care including human, physical, and financial resources. The consequences of technical and interpersonal care are called 'outcomes' (Donabedian 1980).

Quality in healthcare is multidimensional including six dimensions: effectiveness, acceptability, efficiency, access, equity, and relevance (Maxwell 1992). Maxwell pointed out that 'medicine has essential roles at the level of both the individual and the community' (Maxwell 1992, p. 175).

High quality of care means that patients receive only the procedures, tests, or services for which the desired health outcomes exceed the health risks by a sufficiently wide margin; and that each of these procedures or services is performed in a technically excellent manner and all patients are treated in a humane and culturally appropriate manner and are invited to participate fully in deciding about their therapy (Brook et al. 2000, p. 282).

Quality of care for individuals refers to whether individuals can *access* the health structures and processes of care which they need, and when accessed whether the care is *effective*, consistent with knowledge based care and negotiated between provider and user, leading to the maximisation of health *outcomes* (Campbell et al. 2000, p. 1614).

Quality of care for populations refers to the ability to *access effective* care on an efficient and equitable basis for the optimisation of health benefit/well-being for the whole population (Campbell et al. 2000, p. 1617).

Quality of care is the degree to which health services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge (Institute of Medicine 2001, p. 232).

Quality of care is defined as the degree to which care services influence the probability of optimal patient outcomes (AMA 2012).

Some quality of care definitions are generic, proposing that healthcare services might increase or influence optimal or desired outcomes but these definitions do not mention what healthcare services characteristics would improve outcomes (Institute of Medicine 2001; AMA 2012). Other definitions have included different components such as domains or dimensions (Donabedian 1980; Maxwell 1992; Brook et al. 2000; Campbell et al. 2000). Other authors have suggested frameworks of quality in primary care including access, clinical effectiveness, health promotion, service development and innovation, patient experience, cost-effectiveness, and outcomes (Proctor and Campbell 1999). It has been suggested that disaggregated approaches (including domains or dimensions) that combine these components are more specific in defining quality and therefore facilitate measurement (Campbell et al. 2000). Table 5.1 shows examples of dimensions of quality of care. Some authors have suggested more elements within these dimensions such as Donabedian (1980), Donabedian (1990), Maxwell (1992), Brook et al. (2000), and the Institute of Medicine (2001). For example, Campbell et al. (2000) proposed that quality of care has two dimensions and every dimension has components and subcomponents:

1. Effectiveness:
    - Clinical care: coordination
    - Interpersonal care: coordination
2. Access
    - Geographic and physical access
    - Affordability
    - Availability: organisational access, first contact, comprehensiveness, continuity of care

Some dimensions have similar meanings. Technical care (Donabedian 1980; Brook et al. 2000) and effectiveness (Donabedian 1990; Institute of Medicine 2006; Maxwell 1992) [of clinical care] (Campbell et al. 2000) refer to the provision of scientific knowledge-based care to improve health. The dimensions of interpersonal care (Donabedian 1980; Brook et al. 2000), effectiveness [of interpersonal care] (Campbell et al. 2000), and patient-centred (Institute of Medicine 2006) highlight the interaction between patients and health professionals and the provision of care responding to patient's preferences, needs, and values. Optimality refers to the evaluation of the effects of care related to the cost of the care (Donabedian 1990) and efficiency

(Donabedian 1990; Maxwell 1992; Campbell et al. 2000; Institute of Medicine 2006) refer to a balance between costs and benefits.

Other dimensions are relevant to populations like equity, referring to fair provision of health services (Maxwell 1992). Equity can be horizontal when all people receive effective care, and equity can also be vertical when people with more need obtain greater access to effective care (Campbell et al. 2000). Others are specific, for example 'timely' that is about reduction of waiting times and delays (Institute of Medicine 2006). Structure, process, and outcome have been used to measure quality of care (Donabedian 1966; Maxwell 1992; Brook et al. 2000; Institute of Medicine 2001) and to 'produce a taxonomy of quality of care for individual patients' (Campbell et al. 2000, p. 1615).

My aim is to describe quality of care and to identify whether quality of care components predict diabetes outcomes (see Chapter 4 about management of type 2 diabetes). I focus on two dimensions that involve health professionals' and patients' measures of quality of care (clinical and interpersonal care) and includes a subcomponent that is also a feature of access (continuity of care). The following sections provide a wider description about the dimensions included in this Thesis.

Table 5.1 Dimensions of quality of care

Dimensions	Donabedian (1980)	Donabedian (1990)	Maxwell (1992)	Brook (2000)	Campbell (2000)	IOM* (2006)
Technical care	✷			✷		
Interpersonal care	✷			✷	✷	
Efficacy		✷				
Optimality		✷				
Legitimacy		✷				
Effectiveness		✷	✷		✷	✷
Acceptability		✷	✷			
Efficiency		✷	✷		✷	✷
Equity		✷	✷		✷	✷
Access			✷		✷	
Relevance			✷			
Safe						✷
Patient-centred						✷
Timely						✷

*IOM: Institute of Medicine

5.6.3.1 Continuity of care

Continuity of care has been suggested as a subcomponent of timely access (Campbell et al. 2000). However, Freeman et al. (2007) disagree and suggest distinguishing access and continuity of care because 'whilst access is necessary to enable continuity, difficulties or delays in access can cause some patients in some circumstances to trade-off continuity for early access' (Freeman et al. 2007, p. 48). The distinction between continuity of care and timely access is focused on the provision of care by the same doctor because timely access can imply that patients will not be seen by their usual physician. This trade-off between access and continuity has been found in other studies (Aboulghate et al. 2012; Baker et al. 2007; Cheraghi-Sohi et al. 2007; Cheraghi-Sohi et al. 2008; McDonald et al. 2007). For example, this trade-off can be positive when patients receive whatever they need (Baker et al. 2007) but it can be neutral when they 'accept a decreased value of one attribute for an increase in another' (Cheraghi-Sohi et al. 2007, p. 276). I will focus on continuity of care, measuring whether patients are seen by their usual GP.

The trade-off between rapid access and personal continuity of care can be estimated using discrete choice experiments (Ryan et al. 2001). Discrete choice experiments are used to find out preferences about a service based on its attributes. These attributes are presented to individuals as choice scenarios (Ryan et al. 2001). Discrete choice experiments have been used to find out preferences for out of hours care (Scott et al. 2003), emergency services during GP hours (Gerard and Lattimer 2005), shared decision making (Longo et al. 2006), self-care or professional advice for minor illness (Porteous et al. 2006), access to the GP (Rubin et al. 2006), continuity of care (Turner et al. 2007), booking appointments in general practice (Gerard et al. 2008), patient priorities in primary care consultations (Cheraghi-Sohi et al. 2008), and patient valuation of outcomes related to their long-term condition (Richardson et al. 2009). In terms of continuity of care, Turner et al. (2007) found that patients traded off access for relational continuity when they had routine check-ups. Patients preferred to wait (delayed access, >4 days) to see a GP they knew (relational continuity).

Continuity of care has been proposed as a multidimensional concept including five types of continuity (Baker et al. 2001; Freeman et al. 2007; Haggerty et al. 2003; Stokes et al. 2005; Turner et al. 2007):

- experienced continuity (patients' experience of a coordinated and smooth progression of care)

- continuity of information (availability of patients' information to every provider)

- cross-boundary and team continuity (effective communication between professionals and services)

- flexible continuity (flexibility to adjust care based on individuals' needs over time)

- longitudinal continuity (provision of care from key professionals)

- relational or personal continuity (maintenance of therapeutic relationships between key professionals and patients)

The multidimensional concept of continuity of care makes it complex to measure and measures of continuity of care focus on specific types, such as interpersonal or relational continuity (Jee and Cabana 2006; Saultz 2003; Saultz and Albedaiwi 2004; Saultz and Lochner 2005). However, most of these measures of interpersonal continuity do not assess therapeutic relationships between providers and patients because the measures include visit patterns or number of providers seen (Saultz 2003). Long-term relationships between patients and practitioners can be identified from medical records but it is not possible to know the nature of this relationship (Saultz 2003). Studies measuring continuity of care tend to interchangeably use continuity and longitudinality when referring to measurement (Jee and Cabana 2006). Starfield (1980) differentiated these terms suggesting that continuity is a 'bridging mechanism between visits' (e.g. medical records) and longitudinality refers to the care over time with a regular source of care (e.g. usual GP or team). I define relational continuity of care as the care over time with a regular GP and assess it using two measures: one based on medical records (objective) and one based on patients' perceptions (subjective).

5.6.3.2 Clinical care

Effectiveness of clinical care refers to the provision of healthcare services based on knowledge and research evidence (Arah et al. 2006; Campbell et al. 2000; Leatherman and Sutherland 2008), clinical expertise, patients' needs and values (Institute of Medicine 2001), and clinical guidelines (Francke et al. 2008).

5.6.3.2.1 Evidence-based medicine

Healthcare services based on knowledge and research evidence (evidence-based medicine) has received some critique about the lack of responsiveness to patient's non-clinical needs and preferences (Miles et al. 2008). Other authors propose that it is possible to provide effective clinical care using evidence-based medicine that includes providers' expertise and patient's needs and values (Arah et al. 2006; Campbell et al. 2000; Institute of Medicine 2001; Leatherman and Sutherland 2008). Effective clinical care also involves making healthcare decisions by providers and patients together. This process is called 'shared decision making'. This is not a new concept. Buetow (1998) wrote a paper about strategies for negotiated care as a form of shared decision making. Although there was little empirical evidence about the adoption of shared decision making in clinical practice in a review (Legare et al. 2010), there are studies proposing practical models and support tools to implement shared decision making into clinical practice (Elwyn et al. 2012a; Elwyn et al. 2012b). There are also some examples of best practices for implementation of shared decision making (Stiggelbout et al. 2012). The implementation of shared decision making into clinical practice is possible when it is part of health policies or health reforms, as in the UK (Coulter et al. 2011).

5.6.3.2.2 Patient-centred care

Good quality of care implies a partnership between healthcare professionals and patients, where healthcare is provided in response of patients' needs, values, and preferences (Arah et al. 2006; Buetow 2011; Greenhalgh and Heath 2010; Institute of Medicine 2001; Leatherman and Sutherland 2008; Mead and Bower 2002; Stewart 2001). This partnership might be modified by patients' self-management, family, and friends because every patient lives in a specific context that affects their 'experience of illness' (Greenhalgh and Heath 2010). Once patients interact with healthcare

professionals within a healthcare system, it is expected that health professionals will respond to patients with patient-centred care. Five aspects of patient-centred care have been suggested from a review of empirical literature (Mead and Bower 2000):

- Biopsychosocial perspective includes not just physiological conditions but also psychological and social aspects that affect people
- The 'patient-as-person' refers to take into account patients' perception of their condition
- Sharing power and responsibility means that patient involvement is expected to achieve 'mutual participation'
- The therapeutic alliance is focused on the doctor's skills to develop a partnership with the patient
- The 'doctor-as-person' refers to the personal characteristics of doctors that influence the relationship with patients and that this relationship might affect patients' outcomes

Patient-centred care interventions have shown improvements in providers' and patients' behaviours (i.e providers' humanistic and empathic behaviours, providers' detection and management of emotional distress, patients' involvement in healthcare discussions) (Lewin et al. 2001). However, there is also empirical evidence that some patients do not want to explore some aspects of patient-centred care such as psychological issues suggesting that 'tailored patient care' might be better than patient-centred care (de-Haes 2006). Other perspectives have suggested that quality of care can be beyond patient centredness (Veldhuijzen et al. 2011). Veldhuijzen et al. (2011) concluded that patient-centred care was part of quality of care as well as organisation of care and public health.

Although patient-centred care is important for the provision of quality of care, there is no empirical evidence in Mexico that healthcare is provided under this perspective. Therefore, I explore some aspects of interpersonal care such as patient–doctor communication and patient satisfaction; however, patient-centred care is not included in this Thesis because it was not expected to happen in this context.

5.6.3.2.3 Advantages and disadvantages of evidence-based medicine

Evidence-based medicine is related to clinical effectiveness (an aspect of quality of care) in this Thesis and it has some advantages and some disadvantages. Although, the advantage of evidence-based medicine is the inclusion of research evidence, clinical expertise, and patient's preferences in the process of clinical decisions (Haynes et al. 2002; Lambert 2006; Lohr 2004; Satterfield et al. 2009), it also has some limitations. One limitation is the translation of research evidence into clinical practice. For example, research evidence comes from specific populations and is based on an 'average' patient, making it difficult to translate it into practice because patients in the real world have particular individual characteristics (Heath 2008; Howick 2011). Therefore, evidence-based clinical recommendations, that are suitable for some patients, are often not focused on individual patients (Avorn and Fischer 2010). A patient's real world is complex and this complexity requires 'clinical autonomy' (Campbell and Eriksson 2011). Clinical autonomy has been referred as 'the ability of individual physicians to determine their own clinical practices and to evaluate their own performance' (Harrison and Dowswell 2002, p. 209). One of the dimensions included in this Thesis is effectiveness of clinical care and it will be evaluated in terms of evidence-based clinical recommendations. These recommendations will be compared with clinical care (treatment intensification by GP) extracting data from medical records.

5.6.3.2.4 Process and outcome of care

It has been suggested that process of care includes consulting, referral, and prescribing (Avery et al. 2011; Marshall et al. 2003). Process of care also involves balancing benefits, risks, and patients' values and preferences when health providers make clinical decisions in the provision of medical care (Guyatt and Busse 2006; Heath 2008; Heath et al. 2009). The provision of care might also include negotiating care (Buetow 1998) and providing patient-centred care (Stewart 2001). This balance should be applied when providers intensify medical treatment in patients who do not achieve treatment targets, but this balance involves processes that are not usually captured in medical records (e.g. providers may ask patients whether they are having problems taking prescribed medications without including this information in medical records). There is also a lack of information in medical records about the trade-off between risks and benefits in making clinical decisions (e.g. in patients with cancer, their survival may increase with

the addition of chemotherapy to radiotherapy but the risk of toxicity increases as well as the impact on their quality of life) (Bruner et al. 2004). Patients also have the right to dissent to any medical treatment (Molinelli et al. 2009; Paterick et al. 2008).

Outcomes are the consequences of [structures and processes of] care (Donabedian 1980; Brook et al. 2000; Campbell et al. 2000; Institute of Medicine 2001; AMA 2012). Processes and outcomes of care are two elements included in the research questions of this Thesis (*RQ4, RQ5, and RQ6,* included on page 20). Process of care is one of the predictors, specifically quality of clinical care (treatment intensification by GP) and the outcome is glycaemic control. It is expected that glycaemic control is in part the consequence of treatment intensification.

Quality of care has been measured using a variety of approaches (e.g. satisfaction surveys, interaction analysis, and narrative analysis) (Greenhalgh and Heath 2010). Quality of care is complex and has different dimensions that require being measured using multiple methods. I measure some dimensions of quality (clinical care, continuity of care, and interpersonal care – patient–doctor communication and patient satisfaction with diabetes care) using multiple methods such as data extraction from medical records and interviews with patients. I propose a model to predict diabetes outcomes (Figure 5.2).

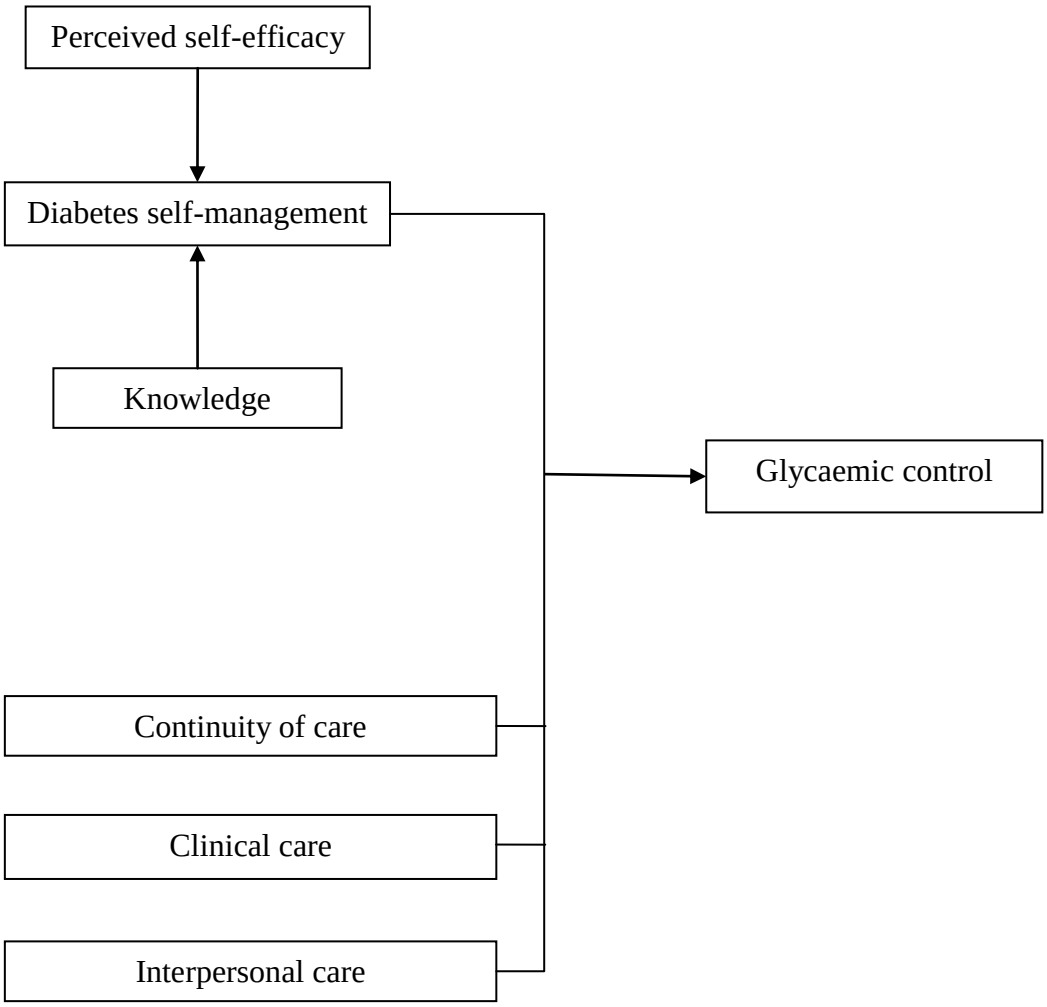
5.6.3.2.5 Cost-effectiveness of care

Another aspect of effectiveness is the efficient use of resources or the cost-effectiveness of care (Gafni et al. 2008). Clinical evaluations are focused on finding the more effective treatment for individuals. Cost-effectiveness refers to economic evaluations to find 'the more efficient use of resources' (Gafni et al. 2008, p. 99) with a population approach helping decision makers in the allocation of available resources. Therefore, cost-effectiveness of care is relevant to population approaches of quality of care as defined in Box 5.6 by Campbell et al. 2000 (quality of care for populations). I do not address cost-effectiveness of care and I focus on effectiveness of clinical and interpersonal care.

This section described quality of care and identified the components that are measured in this Thesis: continuity of care, clinical care, and interpersonal care. These

components of quality of care are included in a model proposed to predict diabetes outcomes (Figure 5.2).

Figure 5.2 Proposed diabetes self-management and quality of care model



5.7 Quality of diabetes care in Mexico

This section presents studies from Mexico including the quality of care components which are examined in this Thesis: continuity of care, clinical care and interpersonal care.

Diaz-Apodaca et al. (2010) measured the quality of care provided to Hispanics with diabetes living in the USA–Mexico border region using data from a population-based cross-sectional survey. The aim was to compare quality of diabetes care between USA (n=240) and Mexico (n=226). Glycaemic control (HbA1c levels) was a quality-of-care measure as well as medical treatment defined as the type of diabetes treatment that patients received (oral hypoglycaemic medications, insulin, hypoglycaemic medications plus insulin, and non-oral medication or insulin). Although there was no measure of continuity of care, there was a measure of the number of diabetes-related visits to a doctor during the previous year. The quality of diabetes care was not significantly different between USA and Mexico (Diaz-Apodaca et al. 2010). Mean HbA1c level for patients residing in Mexico was 7.9% (SD 2.6%), 76.3% patients received oral hypoglycaemic medications, and 40% patients visited a doctor seven or more times the previous year. Diaz-Apodaca (2010) concluded that Hispanics are not receiving optimal diabetes control compared to clinical guideline recommendations (HbA1c <7.0%) (ADA 2013;SSA 2000).

Rodriguez-Saldana et al. (2010) examined patients' previous experience with diabetes care from a survey (n=1000). This survey included questions about method of monitoring diabetes, type of diabetes treatment, cardiovascular risk factors, and diabetes complications (Box 5.7). This study shows poor access to diabetes monitoring (HbA1c test) and diabetes education as well as high prevalence of risk factors and diabetes complications (Rodriguez-Saldana et al. 2010). However, measurements were self-reported by patients. Objective measures might show different results.

Box 5.7 Results from a survey about previous experience with diabetes care

Method to monitor diabetes

- Fasting plasma glucose 59.0%
- Capillary blood glucose 50.6%
- HbA1c 5.3%
- None 6.3%

Diabetes treatment

- Nutrition counselling 39.1%
- Diabetes education 21%
- Oral antidiabetic medications 32%
- Insulin 19.8%

Cardiovascular risk factors

- Hypertension 57.9%
- Dyslipidaemia 26.1%
- Obesity 20.9%
- Smokers 15.5%

Diabetes complications

- Diabetic retinopathy 51.1%
- Diabetic neuropathy 25.8%
- Diabetic nephropathy 15.9%
- Blindness 16.3%
- Diabetic foot 10.5%
- Coronary heart disease 3.7%
- Stroke 4.3%
- Amputations 3.8%

Hernandez-Romieu et al. (2011) examined the association of quality of care with glycaemic control in patients with diabetes. Quality of care measurements included whether patients were weighed, had their blood pressure measured, were given explanations about medical treatment and given counselling about diet and exercise by doctors in the most recent consultation (patients' self-report). Glycaemic control was defined as HbA1c ≤7%. In a multivariate logistic model, lack of glycaemic control (HbA1c >9.5%) was the outcome and all quality of care factors were associated with the outcome. Predictors of lack of glycaemic control were: greater duration of diabetes and treatment with oral antidiabetic medications. Three factors were associated with lower HbA1c (<9.5%): access to social security, attending a referral to the nutritionist, and consultation with a doctor in the last 3 months (Hernandez-Romieu et al. 2011). This study was cross sectional, making it difficult to confirm whether quality of care is a predictor of glycaemic control.

Barcelo (2010) evaluated an intervention (pilot study) to improve quality of diabetes primary care using the Chronic Care Model by Wagner in 1999 and the Chronic Illness Breakthrough Series by the Institute for Healthcare Improvement in 2001 (Wagner et al. 1999; Wagner et al. 2001). Ten primary care practices implemented a clinical information system and patients were offered HbA1c and lipid tests at baseline and at the end of the study. Five of the practices were randomly selected to receive the intervention and the other five practices continued with usual care. There is no information about allocation. All practices also provided peer support groups for patients. Health providers from the intervention practices identified areas for improvement using the Chronic Care Model: organisation of care, community linkages, self-management support, delivery system design, decision support, and clinical information system. Teams in the intervention centres received three learning sessions to implement strategies to improve quality of diabetes care. Current referral systems changed as part of the intervention, bringing specialists to primary care centres where patients were seen by a health team. There was also a case manager advisor for patients who were not achieving goals (HbA1c <7%, cholesterol <200 mg/dl, blood pressure <140/90, food and eye examinations performed). These goals were the outcomes. There were 196 patients in the intervention group and 111 in the control group. Intervention group patients improved goals significantly more than control group (HbA1c, cholesterol, and patients receiving foot and eye examinations). There were some activities delivered in both intervention and control groups (clinical information system

and peer support groups) as well as contamination between practices because of the local publicity of the intervention (Barcelo et al. 2010). The authors suggest that contamination might not have affected results because of the differences in the outcomes but there was no analysis of the contribution of every improvement area to the outcomes or of the relative importance of these improvements to the outcomes.

In 2000, an initiative was started to improve quality of primary care in MISS: the Family Medicine Improvement Process (FMIP). Although FMIP included various structure and process improvements, its evaluation was focused on two strategies: family medicine information system and technical medical training (Castro-Rios et al. 2005) described in Box 5.8.

Technical medical training included, as outcome, GP compliance with diagnostic and therapeutic actions on six conditions: type 2 diabetes, hypertension, acute upper respiratory infections in children <5 years old, prenatal care, cervicitis-vaginitis, and health and development in children <5 years old. Type 2 diabetes is the focus on this Thesis; therefore, I present the measures and results of GP compliance with diabetes care which are related to this Thesis (percentage of patients with FBG < 140 mg/dl and management of patients with blood glucose >150 mg/dl). Glycaemic control was defined as FBG < 140mg/dl. Medical records were reviewed to measure compliance before and one month after training. Technical medical training was evaluated in 392 practices (39% of all practices nationwide) including 95812 medical records at baseline and 56021 medical records in the final evaluation (Castro-Rios et al. 2005). Of these medical records, 27% involved patients with type 2 diabetes and the evaluation of GP compliance with diabetes care was performed in these medical records. There were 48% and 59% patients with FBG <140 mg/dl before and after training, respectively. About half of the patients (53%) were managed to improve glycaemic control when they had FBG >150 mg/dl before training, and this percentage was higher after training (79%). There was no definition of the management of patients with high blood glucose but treatment intensification might be included in this management. Final evaluation was performed one month after training; this time might not have been enough to detect changes in blood glucose and changes may drift back to baseline after one month.

Box 5.8 Strategies in the Family Medicine Improvement Process (Castro-Rios et al. 2005; Derbez-del-Pino et al. 2005)

- Family medicine information system / electronic medical record – five modules:
  1. appointment book including scheduled appointments
  2. integral care (e.g. medical records, prescriptions, and leave of absence)
  3. integrated health programmes (e.g. prenatal and child care)
  4. dentistry records
  5. diagnostic auxiliary services (e.g. blood tests and X-rays)

- Technical medical training included clinical practice guidelines for long-term and acute conditions

5.8 Summary

This chapter explored concepts of self-management and quality of care providing a framework to address the first research question in this Thesis (included on page 19).

I needed to identify and define what aspects of self-management and quality of care would be included in this Thesis. Self-management was defined in general terms and then specific aspects of diabetes self-management were identified. Knowledge and self-efficacy were proposed as core variables of self-management.

Quality of care is a complex concept without an agreed definition including different domains or dimensions which have been proposed by different authors. I measure some of these dimensions which are defined in this chapter: continuity of care, clinical and interpersonal care.

This chapter also presents previous empirical literature about self-management and quality of care in Mexico. Some studies have been done in Mexico but these studies do not answer the main research question in this Thesis: *RQ6* (included on page 20).

The next chapter is a literature review of empirical studies of predictors of glycaemic control. The aim of next chapter is to provide information about studies of predictors in a broader context and to find out whether the sixth research question in this Thesis has been answered.

Chapter 6

Systematic review: observational studies

6.1 Introduction

The purpose of this chapter is to present empirical evidence (using a systematic review of observational studies) about the individual contribution and relative importance of both self-management and quality of care in the glycaemic control of patients with type 2 diabetes based on proposed definitions included in Chapter 5. This chapter shows the lack of evidence from previous empirical literature to answer the sixth research question in this Thesis (included on page 20).

The general methodology of systematic reviews is described, followed by the methodology and results of the current review.

Box 6.1 Key points from Chapter 6

- Few studies have examined the relative importance of self-management and quality of care predicting glycaemic control in patients with diabetes
- Most of these studies showed inconsistent results and used incomparable methods
- There are methodological deficiencies in previously published research, and few studies met all of relevant quality criteria

6.2 Systematic review

This systematic review was done to make sure that the sixth research question in this Thesis (included on page 20), identified by preliminary literature reviews, has not already been addressed within the published literature.

Before describing the review conducted, the following paragraphs discuss the methodology and characteristics of a systematic review.

Systematic reviews have been used to collate, evaluate, and interpret empirical and available evidence relevant to a particular question (Glasziou 2001; Higgins and Green 2011). Higgins and Green (2011) suggested key characteristics of systematic reviews:

- A clearly stated set of objectives with predefined eligibility criteria for studies
- An explicit, reproducible methodology
- A systematic search that attempts to identify all studies that would meet the eligibility criteria
- An assessment of the validity of the findings of the included studies, for example through the assessment of the risk of bias
- A systematic presentation, and synthesis, of the characteristics and findings of the included studies

Although many systematic reviews are about randomised controlled trials (RCT), systematic review methodology can be used with observational studies to test aetiological hypotheses and to examine risks of daily life (i.e. smoking) (Egger et al. 2001). Aetiological hypotheses test cause–effect relationships.

The systematic review in this chapter was focused on observational studies to investigate the individual contribution and relative importance of self-management and quality of care in the glycaemic control. The review includes the six characteristics of systematic reviews suggested by Higgins and Green (2011): clear objectives, explicit eligibility criteria, a systematic search, quality assessment of studies, methodology (data extraction process and analysis), and a narrative analysis of results.

6.3 Individual contribution and relative importance of self-management and quality of care to the control of type 2 diabetes: systematic review

6.3.1 Objective

This systematic review aimed to identify, assess, and synthesise studies of self-management and quality of care, to evaluate the individual contribution and relative importance of these factors in predicting glycaemic control in patients with diabetes.

6.3.2 Eligibility criteria for studies

This review included only observational studies to explore factors which are potentially not good candidates for an intervention, for example, the unethical assignment of patients to a control group who receive no treatment intensification even though they need it.

Observational studies are used to collect data showing what is happing in a defined population without any research intervention. Among the main observational designs are cross-sectional, retrospective, and prospective studies (Box 6.2).

Box 6.2 Observational designs

- Cross-sectional studies measure a factor and an outcome at the same time, examining their relationship. The disadvantage of cross-sectional studies is that they are more useful to assess the existence of a relationship between variables than to establish causality because 'it may be very difficult to determine whether the exposure or outcome came first' (Egger et al. 2001, p. 233). Example: a cross-sectional study examining the relationship between self-management behaviours and health outcomes (i.e. HbA1c) (Compean-Ortiz et al. 2010).

- Retrospective studies trace a population sample backwards in time to ascertain if a risk factor had an effect on an outcome. The use of routine data collected previously is the main advantage of retrospective studies. However, if data collection involves retrospective measurements (self-report), it is more likely that recall bias might affect the results. Recall bias refers to differences in reports from memory (Grimes and Schulz 2002). For example, in case-control studies, the motivation to remember can be different from cases (people with a condition) to controls (healthy people). Cases tend to try harder remembering what might have caused their condition than controls (Grimes and Schulz 2002). Example: a case-control study analysing the association between quality of care (GPs' guideline adherence) and the occurrence of stroke (de Koning et al. 2005).

- Prospective studies follow up a sample over time to monitor if a risk factor has an effect on an outcome over that period of time. A prospective study is the best observational design to ascertain causality because it is expected that the risk factor precedes the effect (Grimes and Shulz 2002). The disadvantage of prospective studies is that follow-up can involve significant expense and likely attrition over time, which can lead to bias (Woodward 1999). Example: Lopez-Portillo et al. (2007) evaluated health outcomes (i.e. fasting blood glucose) before and after health education in patients with diabetes and hypertension.

The inclusion and exclusion criteria for this review are based on the proposed eligibility criteria by Higgins and Green (2011), Glasziou (2001), and Egger et al. (2001).

Inclusion criteria

- Study population: adult patients with diabetes
- Context: primary and secondary care
- Factors: self-management and quality of care
- Outcome: HbA1c
- Type of study: observational
- Papers published in English and Spanish

Children were not included because diabetes management differs with patient age (ADA 2013). The restriction of English and Spanish papers was because of lack of time and funds for translation.

Exclusion criteria

- Studies only including patients with type 1 diabetes
- Protocol without results or data

Pharmacologic treatment for patients with type 1 diabetes is restricted to the use of insulin.

6.3.3 Search methods for the identification of studies

MEDLINE and EMBASE are two of the most important sources of health-related studies that have been suggested for systematic reviews of RCTs (Higgins and Green 2011) as well as for systematic reviews of observational studies (Glasziou 2001; Egger et al. 2001). MEDLINE is a biomedical database developed by the National Library of Medicine (USA) covering over 3000 health-related journals (The University of Manchester 2012b). EMBASE is a biomedical and pharmacological database with a European focus (The University of Manchester 2012a). It is recommended to use both

databases to perform a comprehensive search because there is only approximately 30% overlap between MEDLINE and EMBASE databases (Suarez-Almazor et al. 2000).

I performed the searches using both databases via OVIDSP, which is a technology to access and search information in databases like MEDLINE and EMBASE (The University of Manchester 2012c).The search period covered the earliest date available to the date of the search (March 2009, week 4). On this date, MEDLINE provided information in the period from 1950 to 2009 and EMBASE from 1980 to 2009. The development of the search strategies was an iterative process. The final search strategy and the results are shown in Table 6.1.

Table 6.1 Results of the search strategy to identify papers of predictors of glycaemic control

Database: Ovid MEDLINE(R) <1950 to March Week 4 2009>			Database: EMBASE <1980 to 2009 Week 14>		
Search #	**Keywords**	**Results**	**Search #**	**Keywords**	**Results**
1	glucose adj5 control.ab	8830	1	glucose adj5 control.ab	8383
2	glycaemic adj5 control.ab	3050	2	glycaemic adj5 control.ab	3249
3	glycemic adj5 control.ab	6637	3	glycemic adj5 control.ab	6531
4	HbA1c adj5 control.ab	885	4	HbA1c adj5 control.ab	853
5	HbA1c adj5 levels.ab	1654	5	HbA1c adj5 levels.ab	1634
6	hemoglobin adj5 a1c.ab	2093	6	hemoglobin adj5 a1c.ab	1667
7	haemoglobin adj5 a1c.ab	392	7	haemoglobin adj5 a1c.ab	330
8	1 or 2 or 3 or 4 or 5 or 6 or 7	20417	8	1 or 2 or 3 or 4 or 5 or 6 or 7	19538
9	risk factors.mp	434359	9	risk factors.mp	140788
10	factors adj5 associat*.mp	62170	10	factors adj5 associat*.mp	54237
11	associat*.mp	1824857	11	associat*.mp	1708176
12	characteristics adj5 associat*.mp	11573	12	characteristics adj5 associat*).mp	10096
13	predictive factors.mp	5412	13	predictive factors.mp	5226
14	predict*.mp	577745	14	predict*.mp	511149
15	determinant.mp	48646	15	determinant.mp	42502
16	9 or 10 or 11 or 12 or 13 or 14 or 15	2536730	16	9 or 10 or 11 or 12 or 13 or 14 or 15	2168987
17	8 and 16	8376	17	8 and 16	8159
18	case-control.ab	40884	18	case-control.ab	37957
19	cohort.ab	112386	19	cohort.ab	104749
20	cross-sectional.ab	81680	20	cross-sectional.ab	70676
21	epidemiologic.ab	30042	21	epidemiologic.ab	25884
22	follow-up.ab	368523	22	follow-up.ab	336569

Database: Ovid MEDLINE(R) <1950 to March Week 4 2009>			Database: EMBASE <1980 to 2009 Week 14>		
Search #	**Keywords**	**Results**	**Search #**	**Keywords**	**Results**
23	longitudinal.ab	72858	23	longitudinal.ab	61336
24	models.ab	263065	24	models.ab	240226
25	national level.ab	2471	25	national level.ab	1949
26	observational.ab	30933	26	observational.ab	30035
27	population-based.ab	35947	27	population-based.ab	33174
28	prospective.ab	194290	28	prospective.ab	182629
29	retrospective.ab	145004	29	retrospective.ab	131151
30	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1134048	30	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1028689
31	8 and 16 and 30	2499	31	8 and 16 and 30	2421

6.3.4 Quality assessment of studies

The quality of studies was assessed using three criteria for cross-sectional and retrospective studies, and four criteria for prospective studies. The sample size was also used as an additional measure of quality for all studies (Dattalo 2008). Cross-sectional studies were assessed using quality criteria 1–3 because these studies do not include a follow-up which is included in criterion 4. Retrospective studies were assessed using quality criteria 2–4 because it was expected that these studies would require data extraction from medical records and non-response rate would not be applicable. Prospective studies were assessed using quality criteria 1–4 because these types of studies were expected to report information related to all criteria.

1. non-response rate at baseline for cross-sectional studies, for prospective studies non-response rate at baseline or at follow-up <40%
2. random selection of sample from population, as opposed to other methods such as convenience sampling
3. statistical control of confounders (at least age and/or time with diabetes)
4. at least three months of follow-up to detect changes in HbA1c levels and/or glycaemic control

Random sample selection was used to assess external validity because a random sample is more likely to be representative of a target population (Bland 2000). Internal validity was assessed through the statistical control of factors that may affect the relationship between predictors (quality of care and self-management) and glycaemic control (Woodward 1999). The main factors affecting this relationship are duration of diabetes and age. In the natural history of diabetes, glucose levels increase over time due to both duration of diabetes and age (Ramlo-Halsted and Edelman 1999). A minimum of three months of follow-up was used to detect changes in HbA1c levels as this is the recommended time to monitor patients' blood glucose (National Collaborating Centre for Chronic Conditions 2008). Sample size determines the precision of the sample estimates (confidence intervals) and the power to reject null hypothesis (Dattalo 2008).

6.3.5 Data extraction process

Data extraction was performed by one reviewer (YM) from the selected studies. Data extraction process involved two steps:

Step 1

Data were entered into six tables.

The first table included eight columns with information about general characteristics of the studies (author and year of publication, study design, context, sample size and gender, age, type of diabetes, duration of diabetes, and the outcome).

The second table included six columns with information on study quality (author and year of publication, study design, sample selection, adjustment for confounding, non-response at baseline, and non-response at follow-up).

The third table included seven columns with the measurements for each self-management domain (author and year of publication, knowledge, medication adherence, diet, exercise, self-monitoring of blood glucose (SMBG), and problem-solving).

The fourth table included four columns with the measurements for each quality of care variable (author and year of publication; treatment intensification and continuity of care as defined in Chapter 5; as well as other quality of care variables).

The fifth table included seven columns with the results for each self-management domain (author and year of publication, knowledge, medication adherence, diet, exercise, SMBG, and problem-solving as defined in Chapter 5).

The sixth table included four columns with the results for each quality of care variable (author and year of publication; clinical inertia, pharmacologic management or intensification of medication; continuity of care; and other variables).

Step 2

Data were organised into four tables by each self-management domain and each quality of care domain resulting in 28 tables. The four tables contained the following information: the first table included measurements used in each publication; the second table included the general characteristics of the studies described above omitting two columns because these were inclusion criteria (type of diabetes, the outcome); the third table included information to qualify the studies described above adding time of follow-up; and the fourth table included the results found in each publication.

Data were extracted by a single author for the purposes of this Thesis, although if the review were to be published, all extractions would be checked by a second reviewer via independent extraction.

6.3.6 Analysis

The results were analysed by predictor (i.e. self-management knowledge, self-management behaviours, and quality of care as defined in Chapter 5).

The analysis was in narrative form instead of a meta-analysis because it has been suggested that meta-analysis of observational studies has the risk of 'precise but spurious results' (Egger et al. 2001, p. 211). The results could be precise with the inclusion of large observational studies, but observational studies are likely to be affected by confounding factors or biases.

The analysis in the current review explored the relationships between each predictor and HbA1c, assessing the direction of the relationship (positive, negative, or no relationship) between predictors (self-management, quality of care) and outcome (HbA1c) in each study, and exploring the patterns of those relationships within different study designs (cross-sectional, retrospective and prospective). It has been suggested that effective self-management (Deakin et al. 2005; Gary et al. 2003; Norris et al. 2001; Sarkisian et al. 2003) and quality of care (Knight et al. 2005; Piatt et al. 2006; Pimouguet et al. 2011; Renders et al. 2001; Shojania et al. 2006) improve diabetes outcomes (i.e. glycaemic control). In the current review, a positive relationship denotes that better self-management or quality of care was related to lower HbA1c levels. Negative relationship

denotes that better self-management or quality of care was related to higher HbA1c levels.

When describing individual studies, information was provided on their quality, based on the number of quality criteria fulfilled (see 'Quality assessment of studies', section 6.3.4) and the sample size, to help the reader assess the impact of quality on the patterns identified in the review.

The relative importance of self-management and quality of care predicting glycaemic control was identified in the analysis section of the studies that included both factors. Measures of relative importance could vary, but might include differences in the statistical significance of each predictor, or more precise quantitative measures of relative importance, such as standardised regression coefficients where both measures are included in the same regression equation.

6.3.7 Results

The results of the search # 31 of both MEDLINE and EMBASE databases were reviewed by YM (see Table 6.1). In total, 48 potentially relevant papers were selected: 17 on quality of care and 31 on self-management. The full texts of these 48 papers were reviewed to confirm that the aim was to evaluate the individual contribution and/or relative importance of both self-management and quality of care in the glycaemic control of patients with type 2 diabetes.

Twenty-three studies were excluded for reasons listed in Table 6.2.

Twenty-five of the 48 studies aimed to evaluate the individual contribution and/or relative importance of both self-management and quality of care in the glycaemic control of patients with type 2 diabetes. These 25 studies were included in the review. Most of the studies used a cross-sectional design (n=13, 52%), three papers (12%) used a retrospective design and eight papers (32%) used a prospective design. Only one paper used a combination of cross-sectional and prospective designs (Table 6.3).

Table 6.3 shows study (author and year of publication), methods (including quality criteria and sample size), participants, predictors, and results. Every study design was

assessed based on three or four quality criteria (three quality criteria for cross-sectional and retrospective studies and four quality criteria for prospective studies; specific quality criteria were defined in section 6.3.4 above). Quality criteria are shown per study based on its design (i.e. Klein et al. 1993 met one of three quality criteria for retrospective studies).

Twenty-three studies examined the relationship between self-management and glycaemic control. In terms of the main aims of the review, only two studies examined the relationship between both self-management and quality of care with glycaemic control.

Table 6.2 Reasons for excluded studies

Authors	Reasons for exclusion
	QUALITY OF CARE
Bebb et al. 2005	The aim was to identify the association between practice characteristics and HbA1c
Cook et al. 1999	The aim was to examine the impact of a management programme in a diabetes unit not primary care
Dolovich et al. 2004	The aim was to develop and pilot test a questionnaire to assess continuity of care
Grant et al. 2007	The aim was to assess the relationship between patients' adherence and treatment intensification but the outcome was not glycaemic control
Hansen et al. 2003	The aim was to examine the predictive value of GP characteristics on the course of annual HbA1c measurements
Huppertz et al. 2009	The aim was to measure the association between current treatment and glycaemic control
Jackson et al. 2005	The aim was to examine the relationship between organisational characteristics and HbA1c levels
Otieno et al. 2003	The aim was to determine glycaemic control of ambulatory diabetic patients
Resnick et al. 2006	The aim was to analyse achievement of clinical practice recommendations but only regarding patients' characteristics and not about providers as an element of quality of care
Rodriguez-Moctezuma et al. 2003	The aim was to determine which family physicians' characteristics are associated to glycaemic control
Street, Jr. et al. 1993	The aim was to examine nurse–patient communication and the relationship to metabolic control, but participants attended diabetes education (intervention)
Toth et al. 2003	The aim was to evaluate the quality of diabetes care in a cohort of patients with type 2 diabetes
Trivedi et al. 2005	The aim was to assess changes over time in quality of care, but quality of care was not evaluated as a predictor of glycaemic control
Tuerk et al. 2008	The aim was to investigate physician-related effects on glucose management
Ziemer et al. 2005	The aim was to determine whether inadequate treatment intensification could contribute to high levels of HbA1c but glucose level was determined using a combination of home glucose monitoring values, HbA1c levels, and other laboratory determinations

Authors	Reasons for exclusion
	SELF-MANAGEMENT
Dasgupta et al. 2007	The aim was to present the study protocol of a research about walking behaviours and glycaemic control
Goldman and Smith 2002	The aim was to examine differences by education in treatment adherence in patients with diabetes, but the outcome was self-reported health status
GSEDNu 1997	The aim was to ascertain nutritional patterns in patients with diabetes
Heisler et al. 2005	The aim was to examine the correlation between patients' knowledge of HbA1c levels and actual HbA1c levels
Murata et al. 2004	The aim was to identify clinical and behavioural factors associated with glucose variability in type 2 diabetes but blood glucose was measured by patients (self-monitoring of blood glucose)
Navarro Cardenas et al. 2000	The aim was to determine patient's level of information and attitude to diabetes and their association with glycaemic control, but glycaemic control was measured using FBG levels
Tseng et al. 2005	The aim was to investigate seasonal variations in monthly HbA1c levels
Wilson et al. 1986	The aim was to identify psychosocial variables as predictors of self-care and glycaemic control but there was no evaluation of the relationship between self-care and glycaemic control

Table 6.3 contains a description and the results of included studies. Fourteen studies were based in primary care (56%) and eleven studies were based in both primary care and hospitals or other contexts (i.e. national sample). Two-thirds of studies were carried out in the United States (64%). Most of the studies showed age as a mean (72%), eight of these 18 studies stratified age means by diabetes treatment, frequency of SMBG, type of diabetes, or HbA1c levels. Age means were from 40.4±12.6 to 68.4±13.1. Length of time with diabetes was not consistently reported, 40% of studies showed diabetes duration as a mean and 36% of studies did not report that data. The quality of the studies and results are described and critiqued by predictor in the paragraphs below.

6.3.7.1 Global self-management

Global self-management refers to measures that provide a total score of self-management. Three studies examined the relationship between self-management and HbA1c using global measurements: global self-care scale, self-care diet and exercise scale, and patient education scale (Blaum et al. 1997; Ng et al. 2005; Nichols et al. 2000).

The cross-sectional study of Blaum et al. (1997) included 393 participants, met 1/3 quality criteria, and found that poor global self-care was associated with HbA1c levels >11%. Nichols et al. (2000) used a cross-sectional study and reported that less attention to self-care (combined diet and exercise) predicted worse glycaemic control (2/3 criteria, n=1178). The prospective study of Ng et al. (2005) showed that global diabetes self-care was not a predictor of HbA1c at baseline nor at 3 years follow-up (3/4 criteria, n=500).

6.3.7.2 Self-management knowledge

Three studies examined the relationship between self-management knowledge and HbA1c. Self-management knowledge measurements included: patient confidence/ knowledge questionnaire; clinician interview (patient's understanding of diabetes); and patients' knowledge about their diabetes medications (Hartz et al. 2006; Johnson et al. 2002; McPherson et al. 2008).

Of the two cross-sectional studies, Johnson et al. (2002) reported no relationship between self-management knowledge (3/3 criteria, n=609) and HbA1c, while McPherson et al. (2008) reported a positive relationship (2/3 criteria, n=44). The retrospective study of Hartz et al. (2006) (1/3 criteria, n=69) reported an association, where a good understanding of diabetes was more frequent in patients with HbA1c <7%.

6.3.7.3 Self-management medication adherence

Four studies examined the relationship between self-management medication adherence and HbA1c. Self-management medication adherence measurements included: compliance with treatment questionnaire; self-reported medication adherence; clinician interview (patient's adherence to recommendations of medications); and self-reported compliance (Hartz et al. 2006; Johnson et al. 2002; O'Connor et al. 2004; Singh and Press 2008).

Johnson et al. (2002) conducted a cross-sectional study (3/3 criteria, n=609) and reported no relationship between self-management medication adherence and HbA1c. Hartz et al. (2006) conducted a retrospective study (1/3 criteria, n=69) and reported no relationship between self-management medication adherence and HbA1c. Two prospective studies reported an association. O'Connor et al. (2004) (4/4 criteria, n=1794) found that patients who took medication as prescribed had lower HbA1c levels at follow-up. Singh and Press (2008) (2/4 criteria, n=130) found that compliant patients had significantly lower HbA1c levels than non-compliant patients.

6.3.7.4 Self-management diet

Three studies examined the relationship between self-management diet adherence and HbA1c. Self-management diet adherence measurements included: semi-quantitative food frequency questionnaire; clinician interview (patient's adherence to recommendations on diet); and a single 24-h dietary recall (Grylls et al. 2003; Hartz et al. 2006; Xu et al. 2007).

The cross-sectional study of Grylls et al. (2003) (2/3 criteria, n=150) reported that increasing dietary fat was associated with increasing HbA1c. The cross-sectional study

of Xu et al. (2007) (3/3 criteria, n=1284) reported that higher fat intake was associated with higher HbA1c. The retrospective study of Hartz et al. (2006) (1/3 criteria, n=69) reported that good diet adherence was more frequent in patients with HbA1c <7%.

6.3.7.5 Self-management exercise

One study examined the relationship between self-management exercise adherence and HbA1c. Self-management exercise was measured with a physical activity questionnaire (Grylls et al. 2003).

Grylls et al. (2003) (2/3 criteria, n=150) reported that moderate physical activity was associated with increased HbA1c levels compared with low physical activity.

6.3.7.6 Self-monitoring of blood glucose

Thirteen studies examined the relationship between SMBG and HbA1c. Self-management SMBG measurements included: use, frequency, duration, and/or compliance of SMBG using chart review, databases, records, questionnaires, or interviews (Davis et al. 2006; Evans et al. 1999; Franciosi et al. 2001; Franciosi et al. 2005; Harris 2001; Hartz et al. 2006; Johnson et al. 2002; Karter et al. 2001; Karter et al. 2006; Klein et al. 1993; Murata et al. 2009; Ng et al. 2005; Schutt et al. 2006; Tengblad et al. 2007).

Of the five cross-sectional studies, three reported no relationship between self-management SMBG and HbA1c. One study (Harris 2001) did not find a relationship between SMBG and HbA1c for patients treated with insulin, oral agents, or diet alone (2/3 criteria, n=1305). Johnson et al. (2002) reported that patient compliance with glucose monitoring was not significantly associated with HbA1c (3/3 criteria, n=609). Tengblad et al. (2007) (2/3 criteria, n=896) reported no differences in HbA1c between users and non-users, and frequency of SMBG in any therapy category (diet only, oral agents, or insulin). Franciosi et al. (2001) reported an association, where a non-insulin-treated patient with high frequency of SMBG (≥1 timer per day or ≥1 times per week) was related to significantly higher HbA1c (2/3 criteria, n=2855). Franciosi et al. (2001) also reported an association, where insulin-treated patients able to adjust insulin doses and to practise SMBG with a frequency of ≥1 times per day had lower HbA1c levels as

opposed to those who were not able to adjust insulin doses. Schutt et al. (2006) reported contradictory results in two different populations: patients on oral agents or diet alone with more frequent SMBG had higher HbA1c levels and insulin-treated patients with more frequent SMBG had lower HbA1c levels (1/3 criteria, n=25,500).

Of the three retrospective studies, Klein et al. (1993) reported no relationship between self-management SMBG and HbA1c (1/3 criteria, n=228). Hartz et al. (2006) reported a positive relationship between patients with good glucose monitoring adherence and HbA1c <7% (1/3 criteria, n=69). Evans et al. (1999) (1/3 criteria, n=1597) reported a positive relationship between patients with type 1 diabetes who obtained one strip per day to measure their blood glucose by SMBG and lower HbA1c levels. Evans et al. (1999) also reported no relationship between number of strips dispensed to patients with type 2 diabetes and HbA1c.

Of the five prospective studies, Ng et al. (2005) (3/4 criteria, n=500) reported no relationship between SMBG and HbA1c. Karter et al. (2001) reported that more frequent SMBG was significantly associated with lower HbA1c levels (2/4 criteria, n=24,312). Franciosi et al. (2005) found that increasing the frequency of SMBG was associated with slight decrease in HbA1c (3/4 criteria, n=1896). Murata et al. (2009) reported that more frequent SMBG was associated with significantly lower HbA1c (1/4 criteria, n=5862). Karter et al. (2006) (3/4 criteria, n=16,091) found that in a new-user cohort, there was an improvement in HbA1c after initiation of SMBG in all therapy groups (no medication, oral agents, or insulin). Karter et al. (2006) also found that in prevalent users of SMBG on medications, decreases in SMBG frequency were significantly associated with a modest worsening in HbA1c in patients.

Davis et al. (2006) presented two studies: a cross-sectional (data from 2000) and a prospective (data from 2005). The cross-sectional study included 1286 patients and met 2/3 quality criteria. The prospective study included 531 and met 3/4 quality criteria. There was no association between SMBG and HbA1c in any of the cross-sectional and prospective studies (Davis et al. 2006).

6.3.7.7 Self-management problem solving

Two studies examined the relationship between self-management problem solving and HbA1c. Self-management problem solving measurements included: a social problem solving scale and a health problem solving scale (Hill-Briggs et al. 2006; Hill-Briggs et al. 2007).

Hill-Briggs et al. (2006) (2/3 criteria, n=65) reported that inadequate problem solving style was significantly associated with increased HbA1c. In the other study, Hill-Briggs et al. (2007) (2/3 criteria, n=78) found that effective health-related problem solving was associated with lower HbA1c levels.

There was no study just looking at quality of care as predictor of glycaemic control, but there were two studies including both self-management and quality of care as predictors of glycaemic control.

6.3.7.8 Self-management and quality of care

Two studies examined the relationship of both self-management and quality of care with HbA1c. Self-management was measured in terms of: diet and exercise adherence including questionnaires of stages of change for diet and exercise; and medication adherence using prescription databases. Quality of care was measured in terms of continuity of care and effectiveness of clinical care. Continuity of care was measured with an index of patient's visits with the same provider using information from medical records. Effectiveness of clinical care was measured using automated databases of doctors' treatment intensification regarding an increase in either number of drug classes, daily dosage of at least one ongoing drug class, or a switch to medication in a different drug class (Parchman et al. 2002; Schmittdiel et al. 2008).

The cross-sectional study (Schmittdiel et al. 2008) reported that patients with no evidence of poor adherence and under treatment intensification were more likely to achieve HbA1c levels <7% (0/3 criteria, n=122,967). The prospective study of Parchman et al. (2002) (4/4 criteria, n=265) hypothesised that the relationship between continuity of care and glycaemic control was mediated through stages of change for diabetes self-management diet and exercise. Parchman et al. (2002) reported that

patients advanced in stages of change for diet had smaller increase in HbA1c levels than other patients (standardised coefficient: −0.11; t-test: −2.23; P <0.03) and that improvement in continuity of care was significantly associated with lower HbA1c levels (standardised coefficient: −0.17; t-test: −3.08; P <0.002). Parchman et al. (2002) also reported that the relationship between continuity of care and glycaemic control was significantly mediated by advancement in diet stage of change (t-test: −11.33; P <0.01). This mediation analysis showed that patients with lower HbA1c at follow-up had received more continuity of care and they also advanced more in the stages of change for diet.

Table 6.3 Characteristics and results of included studies

Study	Klein 1993
Methods	Study design: Retrospective Time of follow-up: 1 year Sample selection: Not given Adjustment for confounding: No statistical adjustment Non response baseline: Not applicable Non response follow-up: Not applicable Quality criteria: 1/3
Participants	Context: Primary care Country: United States Sample size: 228 Female: 3.0% (Veterans Affairs Hospital) Age: mean 62 years (range 34 to 79) Diabetes duration: mean 10 years (range <1 – 49)
Predictors	SMBG Measurements: Use, frequency, and duration of self-monitoring of blood glucose (chart review)
Results	There were no differences in HbA1c between patients using SMBG and those not (11.37 vs 11.32). There were no statistically or clinically significant differences (P =0.35) in HbA1c among patients had used SMBG >6 months (11.6 ±3.5%), patients had used SMBG <6 months (10.3 ±3.0%), and patients had used only urine monitoring (11.3 ±3.6%). There were no statistically significant differences (P =0.65) in HbA1c among patients testing SMBG once daily (11.6 ±3.6%), patients testing SMBG twice daily (10.9 ±2.8%), and patients testing SMBG > twice daily (11.1 ±3.5%).
Study	Blaum 1997
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Population-based sample of community-dwelling patients with type 2 diabetes Adjustment for confounding: Independent variables with significant associations or theoretical importance were test in a multivariate model (body mass index (BMI), insulin treatment, total cholesterol, sex, and age) Non-response baseline: 50.0% Non-response follow-up: Not applicable Quality criteria: 1/3
Participants	Context: Primary care Country: United States Sample size: 393 Female: 53% Age: 63.1 ±11.1 years* Diabetes duration: 8.9 ±7.8 years*
Predictors	Self-management diet, exercise, and medication adherence Measurements: Global self-care scale
Results	Poor global self-care was associated with HbA1c >11.6% (OR =1.85, 95% CI: 1.27–2.71, P <0.005)

Study	Evans 1999
Methods	Study design: Retrospective Time of follow-up: 3 years Sample selection: Population-based register Adjustment for confounding: Adjustment was done for gender Non response baseline: Not applicable Non response follow-up: Not applicable Quality criteria: 1/3
Participants	Context: Hospital and primary care Country: United Kingdom Sample size: type 1 diabetes =807, type 2 diabetes =790 Female: type 1 44.1%, type 2 51.9% Age: Age was categorised into five groups stratified by gender and type of diabetes Diabetes duration: Not given
Predictors	SMBG Measurements: Number of blood glucose monitoring reagent strips dispensed to patients (database)
Results	Total number of reagent strips dispensed was a predictor of lower levels of HbA1c in patients with type 1 diabetes (P <0.001) Total number of reagent strips dispensed was not a predictor HbA1c in patients with type 2 diabetes (P =0.35)
Study	Nichols 2000
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: All eligible patients of a large non-profit health maintenance organisation Adjustment for confounding: Adjustment was done for age and years since diagnosis among other confounders Non response baseline: 11.6% Non response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Primary care Country: United States Sample size: 1178 Female: Not given Age: patients receiving insulin alone mean 65.9 years, patients receiving combination therapy mean 64.3 years Diabetes duration: patients receiving insulin alone mean 16.5 years, patients receiving combination therapy mean 13.5 years
Predictors	Self-management diet and exercise Measurements: Self-care diet and exercise scale
Results	Less attention to self-care regarding diet and exercise predicted worse glycaemic control (P <0.05)
Study	Franciosi 2001
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Convenience – physicians, Random – patients (diabetes clinics), Convenience – patients (general practice) Adjustment for confounding: Adjustment was done for gender, living alone, education, setting of care, age BMI, duration of diabetes, TIBI

	(Total Index Burden Index), HbA1c, frequency of hypoglycaemic symptoms, ability to adjust insulin doses, and number of insulin injections per day Non-response baseline: 17.0% Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Outpatient diabetes clinics, General practice Country: Italy Sample size: 2855 Female: Gender was shown according to frequency of blood glucose self-testing. Percentages were 42.8–50.2% Age: Age was shown according to frequency of blood glucose self-testing. Means were from 61.1 ±11.2 to 63.7 ±9.6 years* Diabetes duration: Diabetes duration was shown according to frequency of blood glucose self-testing. Means were from 8.7 ±7.6 to 12.7 ±9.0 years*
Predictors	SMBG Measurements: Frequency of self-monitoring of blood glucose (questionnaire)
Results	In non-insulin-treated patients, frequency of SMBG ≥1 times per day or ≥1 times per week was related to significantly higher HbA1c levels (P =0.008, and P <0.001). In insulin-treated patients patients able to adjust insulin doses and practising SMBG with a frequency of ≥1 times per day had highly significant lower HbA1c levels as opposed to those who were not able to adjust insulin doses (P =0.01)
Study	Harris 2001
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Stratified probability sample Adjustment for confounding: Adjustment was done for diabetes therapy Non-response baseline: 11.8% Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: National sample Country: United States Sample size: 1305 Female: 56% Age: mean 62.5 years Diabetes duration: Not given
Predictors	SMBG Measurements: Frequency of self-monitoring of blood glucose (questionnaires)
Results	Logistic regression models did not show a relationship between SMBG and HbA1c levels for patients treated with insulin, oral agents, or diet alone (P >0.5)
Study	Karter 2001
Methods	Study design: Prospective Time of follow-up: 1 year Sample selection: Not given

	Adjustment for confounding: Adjustment was done for age, sex, race, education, occupation, income, duration of diabetes, medication refill adherence, clinic appointment "no show" rate, annual eye exam attendance, use of non-pharmacological (diet and exercise) diabetes therapy, smoking, alcohol consumption, hospitalization and emergency room visits, and the number of daily insulin injections Non-response baseline: Not given Non-response follow-up: Not given Quality criteria: 2/4
Participants	Context: Hospitals and outpatient clinics Country: United States Sample size: 24,312 Female: Gender was shown according to type and treatment of diabetes. Percentages were 45.0–59.0% Age: Age was shown according to type and treatment of diabetes. Means were from 40.4 ±12.6 to 62.9 ±10.4 years* Diabetes duration: Diabetes duration was shown according to type and treatment of diabetes. Percentages were 14–82% (0–9 years) and 18–86% (10+ years)
Predictors	SMBG Measurements: Frequency of self-monitoring of blood glucose (pharmacies databases)
Results	More frequent SMBG was significantly associated with lower HbA1c levels (P <0.0001)
Study	Johnson 2002
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Random sample Adjustment for confounding: Adjustment was done by disease duration Non-response baseline: 17.2% Non-response follow-up: Not applicable Quality criteria: 3/3
Participants	Context: Primary care Country: United States Sample size: 609 Female: Not given Age: Not given Diabetes duration: Not given
Predictors	Compliance with treatment and home glucose monitoring, and patients confidence in understanding their disease Measurements: questionnaire including scales of compliance with treatment (three items), compliance with monitoring (four items), and patient confidence (seven items)
Results	Patient confidence, compliance with treatment, and compliance with monitoring were not significantly associated with HbA1c (P =0.33, 0.67, and 0.19, respectively)
Study	Parchman et al. 2002
Methods	Study design: Prospective Time of follow-up: Mean duration between interviews was 18.9 months (range 12–23 months)

	Sample selection: Random sample Adjustment for confounding: In the regression model, independent variables were: baseline HbA1c, total number of visits, number of months since diagnosis of diabetes, and number of days in the study Non-response baseline: Not given Non-response follow-up: 18.7% Quality criteria: 4/4
Participants	Context: Primary care Country: United States Sample size: 265 Female: 71.6% Age: mean 58.7 ±9.7 years* Diabetes duration: 109.7 ±84.9 months*
Predictors	Stages of change for diet and exercise Continuity of care Measurements: Stages of change for diet and exercise questionnaires Continuity index using information from medical records
Results	Patients advanced in stages of change for diet had smaller increase in HbA1c levels than patients did not advance (standardised coefficient: −0.11; t-test: −2.23; P <0.03) Differences were not significant in mean change in HbA1c level between advancers and non-advancers in stages of change for exercise. Therefore, this variable was not included in the regression model. Advancers 0.35 (1.40). No advancers 0.28 (1.82) P >0.05 Improvement in continuity of care was significantly associated with lower HbA1c levels (standardised coefficient:−0.17; t-test: −3.08; P <0.002)
Study	Grylls 2003
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Convenience sample Adjustment for confounding: Adjustment was done for gender, age, per cent energy from saturated fat, per cent energy from alcohol, fibre density, BMI, socioeconomic status, insulin treatment, living arrangement, overall physical activity and interactions between gender and age, and between gender and living arrangement Non-response baseline: 29.0% Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Ambulatory care Country: New Zealand Sample size: 150 Female: 49.3% Age: 65–70 years (38.7%), 71–75 years (31.3%), 76–91 years (30.0%) Diabetes duration: Not given
Predictors	Diet and physical behaviours Measurements: Semi-quantitative food frequency questionnaire, Physical activity questionnaire
Results	Each five-unit increase in energy from dietary saturated fat was associated with 6% increases in HbA1c (P =0.00)

	Participants in the moderate physical activity group, compare with the low, overall activity group had a 7% increase in HbA1c (P =0.03)
Study	O'Connor 2004
Methods	Study design: Prospective Time of follow-up: 1 year Sample selection: Stratified random sample Adjustment for confounding: Adjustment was done for sex, age, education, and duration of diabetes Non-response baseline: 40.8% Non-response follow-up: Not given Quality criteria: 4/4
Participants	Context: Primary care Country: United States Sample size: 1794 Female: 47.6% Age: 61.8 ±13.0 years* Diabetes duration: 10.4 ±10.1 years*
Predictors	Medication adherence Measurements: Self-reported medication adherence
Results	Patients took medication as prescribed had lower HbA1c in the follow-up (P <0.01)
Study	Franciosi 2005
Methods	Study design: Prospective Time of follow-up: 3 years Sample selection: Convenience – physicians, Random – patients (diabetes clinics), Convenience – patients (general practice) Adjustment for confounding: Adjustment was done for gender, age, living alone, years of school education, household income, duration of diabetes, TIBI (Total Index Burden Index), diabetes treatment, BMI, frequency of hypoglycaemic symptoms, setting of care and family support score Non-response baseline: 29.0% Non-response follow-up: 33.6% Quality criteria: 3/4
Participants	Context: Outpatient diabetes clinics, General practice Country: Italy Sample size: 1896 Female: Gender was shown according to frequency of SMBG. Percentages were:SMBG ≥1/day: 50.8%, SMBG ≥1/week: 40.8%, SMBG <1/week/never: 43.5% Age: Age was shown according to frequency of SMBG. Means were: SMBG ≥1/day: 60.5 ±10.4, SMBG ≥1/week: 61.3 ±10.1, SMBG <1/week/never: 63.4 ±9.8 years* Diabetes duration: Duration of diabetes was shown according to frequency of SMBG. Means were: SMBG ≥1/day: 10.3 ±8.3, SMBG ≥1/week: 10.0 ±7.9, SMBG <1/week/never: 8.4 ±7.2 years*
Predictors	SMBG Measurements: Frequency of self-monitoring of blood glucose (questionnaire)
Results	Increasing the frequency of SMBG was associated with a slight decrease in mean HbA1c (P =0.08)

Study	Ng 2005
Methods	Study design: Prospective Time of follow-up: Annually for 3 years Sample selection: Convenience. Patients meeting criteria were consecutively enrolled Adjustment for confounding: Adjustment was done for age at baseline and years since diagnosis among other confounders Non-response baseline: Not given Non-response follow-up: 8.8% 1 year, 14.6% 2 years, 17.8% 3 years Quality criteria: 3/4
Participants	Context: Primary care Country: Singapore Sample size: 500 Female: 54.2% Age: 53.9 ±6.9 years* Diabetes duration: median 7.0 years (4–11)†
Predictors	Diabetes self-care about knowledge and skills in blood glucose control Measurements: eight-item patient educational scale including questions about patients compliance and drug dosing skills with oral hypoglycaemic agents, frequency of urine and blood glucose self-monitoring, skill in testing techniques, knowledge of HbA1c and blood glucose targets, and knowledge of prevention of hyperglycaemia and hypoglycaemia
Results	Global diabetes self-care was not predictor of HbA1c either at baseline (P =0.43) or at 3 years follow-up (P =0.62) Self-monitoring of blood glucose was not predictor of HbA1c either at baseline (P =0.87) or at 3 years follow-up (P =0.38)
Study	Davis 2006
Methods	Study design: Two studies: one cross-sectional and one prospective Time of follow-up: 5 years Sample selection: Convenience Adjustment for confounding: Adjustment was done for age and duration of diabetes among other confounders Non-response baseline: 0.6% Non-response follow-up: 58.7% Quality criteria: 2/3
Participants	Context: Community-based patients Country: Australia Sample size: 1286 Female: 51.2% Age (mean, SD): 64.1 ±11.3 years* Diabetes duration: median 4.0 (1.0–9.0)‡
Predictors	SMBG Measurements: Self-reported SMBG
Results	SMBG frequency was not significantly associated with HbA1c (P =0.71) in the cross-sectional study. In the longitudinal study, HbA1c was not different between patients self-monitored compared with those did not (P ≥0.05)
Study	Hartz 2006
Methods	Study design: Retrospective

	Time of follow-up: 1 year Sample selection: Not given Adjustment for confounding: No statistical adjustment Non-response baseline: Not applicable Non-response follow-up: Not applicable Quality criteria: 1/3
Participants	Context: Primary care Country: United States Sample size: 69 Female: 61.5% Age: Patients with HbA1c <7% had mean age of 60.1 years, patients with HbA1c 7–8% had mean age of 61.5 years, patients with HbA1c >8% had mean age of 56.6 years Diabetes duration: Patients with HbA1c <7%: <5 years 57.7%, patients with HbA1c 7–8%: <5 years 35.7%, patients with HbA1c >8%: <5 years 58.6%
Predictors	Patient self-care behaviours: patient understanding of diabetes, patient adherence to recommendations on glucose monitoring, diet and medication Measurements: Clinician interviews to obtain information about patient self-care behaviours
Results	Good understanding of diabetes was more frequent in patients with HbA1c <7% (P <0.05) Medication compliance was not associated with HbA1c levels Good diet adherence was more frequent in patients with HbA1c <7% (P <0.01) Good glucose monitoring adherence was more frequent in patients with HbA1c <7% (P <0.05)
Study	Hill-Briggs 2006
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Systematic sampling Adjustment for confounding: Adjustment was done for socio demographic variables (gender, education and income) and depressive symptoms Non-response baseline: All participants completed measures Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Primary care Country: United States Sample size: 65 Female: 42% Age: 59.5 ±11.6 years* Diabetes duration: 9.1 ±8.7 years*
Predictors	Social problem solving Measurements: Social Problem-Solving Inventory Revised Short Form (SPSI-R:S). Two domains: 1. Problem-solving style comprises three subscales: rational problem solving, impulsive/careless style, and avoidant style; 2. Problem-solving orientation comprises two subscales: positive problem orientation and negative problem orientation. SPSI-R:S subscale scores were categorised into three categories:

	below average, average, and above average
Results	Avoidant style was statistically significant associated with increased HbA1c (P =0.01). Above Average avoidant style group was associated with worse glycaemic control (P =0.03)
Study	Karter 2006
Methods	Study design: Prospective Time of follow-up: 3 years Sample selection: Not given Adjustment for confounding: Adjustment was done for pre-baseline HbA1c, sex, age, inpatient comorbidity, score, pre-baseline measures of daily insulin injections frequency, diabetes medication refill adherence, diabetes therapies (therapeutic class), appointment 'no show' rate, performance of annual ophthalmology exams, pre-baseline rates of hospital, emergency room, primary care, and specialty visits, primary care provider type, smoking status, neighbourhood level, median family income, residence in a poorly educated neighbourhood, residence in a predominantly working-class neighbourhood, and the length of time between pre- and post-HbA1c tests Non-response baseline: Not given Non-response follow-up: 33.0% Quality criteria: 3/4
Participants	Context: Outpatient clinics, hospitals Country: United States Sample size: 16,091 Female: Gender was shown according to use of SMBG and diabetes therapy. Percentages were 41.9–50.3% Age: Age was shown according to use of SMBG and diabetes therapy. Means were from 53.2 ±18.4 to 67.3 ±11.9 years* Diabetes duration: Not given
Predictors	SMBG Measurements: Average daily SMBG testing frequency (pharmacy records)
Results	In the new-user cohort, there was a marked improvement in HbA1c after initiation of SMBG practice in all three therapy groups: no medication, oral hypoglycaemic agents, or insulin (P <0.0001). In the prevalent-user cohort, patients on medications with subsequent changes in SMBG frequency by one strip daily resulted in a 0.16- and 0.12-point inverse change in HbA1c, respectively (P <0.0001) = increases in SMBG were associated with modest improvements in control
Study	Schutt 2006
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Not given Adjustment for confounding: Adjustment was done for age, diabetes duration, gender, BMI-z-score, treatment centre, and year of therapy Non-response baseline: Not given Non-response follow-up: Not applicable Quality criteria: 1/3

Participants	Context: Primary care Country: Germany, Austria Sample size: Type 1: 19,491, Type 2: 5009 Female: Not given Age: Not given Diabetes duration: Type 1 mean 5.8 years, Type 2 mean 10.3 years
Predictors	SMBG Measurements: Frequency of SMBG (databases)
Results	In patients with insulin-treated type 2 diabetes, more frequent SMBG was associated with better metabolic control (HbA1c reduction of 0.16% for one additional SMBG/day, P <0.0001). In patients with type 2 diabetes on oral antidiabetic drugs or diet alone, more frequent SMBG was associated with higher HbA1c levels (HbA1c increase of 0.14% for one additional SMBG/day, P <0.0001)
Study	Hill-Briggs 2007
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Convenience Adjustment for confounding: Patients' characteristics were not associated with health-related problem solving. Therefore, these variables were not included as covariates Non-response baseline: 14.0% Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Diabetes centre Country: United States Sample size: 78 Female: 59.0% Age: 51.2 ±14.7 years* Diabetes duration: <1–5 years: 35.9%, 6–10 years: 14.1%, 10–20 years: 33.3%, >20 years: 16.7%
Predictors	Patient health-related problem solving Measurements: Health Problem-Solving Scale has seven subscales: 1. Effective problem solving 2. Impulsive/careless problem solving 3. Avoidant problem solving 4. Positive transfer of past experience/learning 5. Negative transfer of past experience/learning 6. Positive motivation/orientation 7. Negative motivation/orientation
Results	Effective health-related problem solving was associated with lower HbA1c levels in total score (P <0.01), and in three subscales: Effective problem solving (P <0.01) Positive transfer of past experience/learning (P <0.001) Positive motivation/orientation (P <0.001)
Study	Tengblad 2007
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Stratified randomised sample Adjustment for confounding: Adjustment was done for age and gender

	Non-response baseline: Not given Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Primary care Country: Sweden Sample size: 896 Female: Gender was shown according to diabetes therapy and use of SMBG. Percentages were 46.9–51.1% Age: Age was shown according to diabetes therapy and use of SMBG. Means were from 64.7 ±11.1 to 68.4 ±13.1 Diabetes duration: Not given
Predictors	SMBG Measurements: Use and frequency of SMBG (medical records and interviews)
Results	There were no differences in HbA1c levels between users and non-users of SMBG in any therapy category (diet only, oral agents, or insulin) P =ns. There was no association between frequency of SMBG tests and levels of HbA1c in the different treatment categories, respectively (diet P =0.62, oral agents P =0.13, insulin P =0.57)
Study	Xu 2007
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: Cluster sampling Adjustment for confounding: Adjustment was done for sex, age, study centre, BMI, duration of diabetes, diabetes treatment, smoking and alcohol drinking, total energy intake, and physical activity Non-response baseline: Non-response rate for the 24-h dietary recall was 5.0% Non-response follow-up: Not applicable Quality criteria: 3/3
Participants	Context: Participants of an epidemiologic study Country: United States Sample size: 1284 Female: 67.3% Age: Age was shown according to gender and HbA1c levels. Means were from 59.1 ±7.6 to 62.4 ±7.5 years* Diabetes duration: Diabetes duration was shown according to gender and HbA1c levels. Medians were 6–12, first-third quartiles were 4–20
Predictors	Macronutrient intake Measurements: Dietary data were collected using a single 24-h dietary recall
Results	Higher total fat and monounsaturated fatty acids (MUFA) and lower carbohydrate intakes were significantly associated with higher HbA1c levels (P <0.05). Poor glycemic control were significantly higher with increasing quintiles of total fat, saturated fatty acids (SFA), MUFA, and protein intake and significantly lower with increasing quintiles of carbohydrates (P <0.01)
Study	McPherson 2008
Methods	Study design: Cross-sectional

	Time of follow-up: Not applicable Sample selection: Convenience Adjustment for confounding: Adjustment was done for age, sex, medical assistance, and the number of oral diabetes medications used Non-response baseline: 10.0% Non-response follow-up: Not applicable Quality criteria: 2/3
Participants	Context: Primary care Country: United States Sample size: 44 Female: 54.6% Age: <65 years: 38.6%, >65 years: 61.4% Diabetes duration: Not given
Predictors	Patients' knowledge about medications Measurements: Diabetes medication knowledge questionnaire
Results	Patients with more knowledge of their diabetes medications had lower HbA1c levels (P <0.0001)
Study	Schmittdiel et al. 2008
Methods	Study design: Cross-sectional Time of follow-up: Not applicable Sample selection: All eligible patients from a healthcare delivery system Adjustment for confounding: No statistical adjustment Non-response baseline: Not given Non-response follow-up: Not applicable Quality criteria: 0/3
Participants	Context: Primary care Country: United States Sample size: 122,967 Female: 47.6% Age: 61.0 ±13.0 years* Diabetes duration: Not given
Predictors	Medication adherence Treatment intensification Measurements: Adherence to medication and treatment intensification were measured using prescription databases
Results	Patients with no evidence of poor adherence and under treatment intensification were more likely to achieve HbA1c levels <7% (P <0.001)
Study	Singh 2008
Methods	Study design: Prospective Time of follow-up: 1 year Sample selection: Convenience Adjustment for confounding: No statistical adjustment Non-response baseline: Not given Non-response follow-up: 11.6% Quality criteria: 2/4
Participants	Context: Diabetic clinic Country: United Kingdom Sample size: 130 Female: 46.9%

	Age: median 51 years (range: 18–72) Diabetes duration: median 11 years (range: 1–35)
Predictors	Patient compliance Measurements: Self report compliance
Results	Compliant patients had significantly lower HbA1c levels (8.3 ±1.4) than non-compliant patients (10.6 ±1.4) at 1 year follow-up (P <0.001)
Study	Murata 2009
Methods	Study design: Prospective Time of follow-up: 2 years Sample selection: Not given Adjustment for confounding: Adjustment was done for patients' treatment status Non-response baseline: Not given Non-response follow-up: Not given Quality criteria: 1/4
Participants	Context: Primary care Country: United States Sample size: 5862 Female: Not given Age: Not given Diabetes duration: Not given
Predictors	SMBG Measurements: SMBG testing rate peer week: 7* total number of glucose test strips/follow-up period (days) (pharmacy files)
Results	After stratifying by treatment group and adjusting for initial oral hypoglycaemic agents (OHA) dose, more frequent SMBG testing was associated with a significantly lower HbA1c in patients with OHA dose unchanged (P =0.04), patients with OHA dose increased and new OHA added (P =0.002), and patients with insulin added (P <0.001)

*Mean ± standard deviation; †Quartile 1 – quartile 3; ‡Interquartile range

6.3.8 Discussion

6.3.8.1 Summary of the results

Twenty-five studies provided 40 tests of the relationship between various dimensions of self-management and quality of care to glycaemic control. These relationships included three studies using global measurements of self-management, four studies stratifying the analysis by patients' characteristics (type of diabetes, insulin treatment, and type of SMBG users), and one study using a combination of cross-sectional and prospective designs. Twenty-four tests showed a positive relationship included in 19 studies but there were just three studies meeting all quality criteria (one cross-sectional and two prospective studies). Negative relationships were shown in three studies and none of these studies met all quality criteria. Nine studies reported 13 tests without any relationship between self-management and glycaemic control and two of these studies met all quality criteria (one cross-sectional and one prospective study). There were only two studies including data on both self-management and quality of care to allow some consideration of the relative importance of these factors but there was no study focusing on the aspects of self-management and quality of care that are included in this Thesis.

6.3.8.2 General critique

Three studies included 'global' measures of self-management (Blaum et al. 1997; Ng et al. 2005; Nichols et al. 2000) and self-management is a multidimensional concept including specific aspects in the management of long-term conditions (i.e. exercise, diet, medications, and monitoring of the condition). It might be possible that global measures of self-management do not provide a broad understanding of the condition management.

Three studies of knowledge used measures that were provided by patients and clinicians (Hartz et al. 2006; Johnson et al. 2002; McPherson et al. 2008). Clinicians' perception of patients' understanding of diabetes might not be as accurate as patients' self-report.

Hartz (2006) used a subjective measure of diet (clinician interview) and the quality was lower. The results reported by Hartz (2006) should perhaps be taken cautiously.

Although Grylls (2003) suggests that physical activity was related to HbA1c levels, the design was cross-sectional, making it difficult to be sure about the direction of the relationship. It might be possible that patients were exercising more, to lower their HbA1c levels.

6.3.8.3 The results in the context of the published literature

The association between knowledge and glycaemic control (HbA1c <7.0%) was not consistent. Two studies reporting an association met only one or two quality criteria. Evidence that knowledge improves glycaemic control has also shown inconsistent results in the published literature using interventions. Norris et al. (2001) performed a systematic review of RCTs including self-management interventions in patients with type 2 diabetes. The interventions focused on knowledge or information; lifestyle behaviours (e.g. diet and exercise); skills to improve glycaemic control and to prevent and identify complications; and coping skills improving psychosocial adjustment. The results showed that only 8 of 21 interventions improved glycaemic control.

Studies examining the relationship between self-management medication adherence and glycaemic control also showed contradictory results. These contradictory results might be because every study used a different measure to evaluate medication adherence. However, the evidence that medication adherence is a potential predictor of glycaemic control is strengthened because an association was found in a prospective study meeting all quality criteria and using a large sample size of 1794 participants (O'Connor et al. 2004). Gary et al. (2003) performed a meta-analysis of RCTs including interventions on diet, exercise, medications (regimen changes or adherence), SMBG, and foot care in type 2 diabetes. The meta-analysis included 18 papers finding that six interventions improved glycaemic control and the largest effect size was found in studies focused on regimen changes or adherence (−0.72; P =0.032).

All three studies examining the relationship between self-management diet and glycaemic control showed a positive relationship. Gary et al. (2003) also reported that studies focused on diet had a large effect size (−0.51; P =0.008).

It is difficult to derive any conclusion about the relationship between self-management exercise and glycaemic control because there was just one study evaluating this

relationship. A systematic review of RCTs found that studies focused on physical activity (eight studies) showed inconsistent results because just two of these studies found significant improvements in glycaemic control (Norris et al. 2001).

Most of the studies in this review examined the relationship between SMBG and glycaemic control. The strongest evidence comes from prospective studies, where four of the five studies found that frequency of SMBG was associated with lower HbA1c levels. These studies met some of the quality criteria (2/4 or 3/4) and used large sample sizes >1896 patients (Franciosi et al. 2005; Karter et al. 2001; Karter et al. 2006). Gary et al. (2003) conducted a meta-analysis to assess the effect of educational and behavioural interventions on glycaemic control finding inconsistent results in SMBG interventions. A study found that SMBG improved glycaemic control showing an effect size of −0.20 (P <0.001). However, glycaemic control worsened after an SMBG intervention in another study (Gary et al. 2003).

Self-management problem solving was associated with glycaemic control in both studies but these studies used cross-sectional designs and had limited sample sizes. Although Gary et al. (2003) found improvements in glycaemic control after problem-solving interventions in a meta-analysis, the effect size was very small (−0.06). Therefore, there is not sufficient evidence about the relationship between problem solving and glycaemic control.

There were two studies examining both self-management and quality of care as predictors of glycaemic control. Parchman et al. (2002) found that continuity of care was better at predicting glycaemic control than diet adherence. However, the difference between the estimates was negligible (standardised coefficients: continuity of care −0.17, t-test −3.08, P <0.002; advanced in stages of change for diet −0.11, t-test: −2.23, P <0.03).

Although, Schmittdiel et al. (2008) were looking at the relative importance of medication adherence and treatment intensification, the authors only analysed the combination of these variables as predictors of glycaemic control without studying their relative contribution. Furthermore, data analysis of this study was limited because the authors only analysed significant differences among patients achieving glycaemic

control without using any regression analysis to establish the relative contribution of medication adherence and treatment intensification over glycaemic control.

6.3.8.4 Strengths and weaknesses

There are some limitations with this review. Searches were performed only in two databases (MEDLINE and EMBASE). Using more databases and other search strategies might have increased the number of studies in the review. Additional databases might include the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Latin American and Caribbean Health Sciences Literature (LILACS), ISIS Web of Knowledge, Applied Social Sciences Index and Abstracts (ASSIA), and the Cochrane Library. However MEDLINE and EMBASE have been considered two of the most important sources to search health-related studies (Higgins and Green 2011). Other search methods might include hand searching and writing to authors of relevant studies and expert reviewers to identify additional studies, especially unpublished work and studies in progress.

6.3.10 Summary

This review identified 25 studies examining the relationship between self-management and quality of care with glycaemic control in patients with diabetes. There were 19 studies finding positive relationships between the predictors (self-management and quality of care) and glycaemic control but there were just three of these studies meeting all quality criteria. There was no study of self-management with a comprehensive measurement of every dimension (knowledge, medication adherence, diet, exercise, SMBG, and problem solving). The review found very limited evidence concerning the relative importance of self-management and quality of care as predictors of glycaemic control.

I will report data on the relative importance of self-management and quality of care as predictors of glycaemic control. To maximise quality, the study will use a prospective design, ensuring that the study is properly powered, and will measure a range of self-management and quality of care variables (defined in Chapter 5), and analysing the individual contribution of each predictor, their relative importance, and possible

interactions. The main study in this Thesis (described in Chapter 8) will answer the six research questions included on pages 19 and 20.

Chapter 7
Summary of research problem and research questions

7.1 Part One: Introduction and literature review

Part One of the Thesis, from Chapters 1 to 6, identified, discussed, and critiqued the relevant literatures and subsequent research questions pertinent to this Thesis, and set the context in terms of primary care within Mexico and type 2 diabetes. It defined self-management and quality of care and presented a systematic review of observational studies, which found limited evidence assessing the individual contribution and relative importance of self-management and quality of care on the glycaemic control of patients with type 2 diabetes. I will therefore answer the following research questions:

RQ1. What are the demographic, clinical, self-management, and quality of care characteristics of patients with type 2 diabetes in primary care?

RQ2. What demographic and clinical factors are related to self-management and quality of care in primary care?

RQ3. What is the relationship within and between self-management and quality of care in primary care?

RQ4. What demographic, clinical, self-management, and quality of care factors are related to glycaemic control at baseline in primary care?

RQ5. What demographic, clinical, self-management, and quality of care factors predict glycaemic control at six-month follow-up in primary care?

RQ6. What is the relative importance of self-management and quality of care in the prediction of glycaemic control at six-month follow-up in primary care?

7.2 Part Two: Empirical research

Part Two of the Thesis will present the methods used to address each of the research questions and to collect empirical evidence about the individual contribution and relative importance of self-management and quality of care on the glycaemic control of patients with type 2 diabetes and the results of this study.

7.3 Part Three: Discussion

Part Three of the Thesis will discuss the results and original contribution of the empirical research in relation to each of the research questions. Part Three will also discuss the methodological strengths and limitations of the approaches taken, the results in the context of the published literature, recommendations for future research, and the implications for policy and practice.

Chapter 8
Methods

8.1 Introduction

This chapter describes the methodology used to address the six research questions for this Thesis included on pages 19 and 20.

These research questions are tested using a longitudinal cohort study, as described in section 8.3. The analysis of baseline data addresses RQ1–4, whilst a longitudinal analysis addresses RQ5 and RQ6. The study design is described in section 8.4, including a description of the context, patient selection criteria, sample size, and sampling methods. Section 8.5 describes data collection procedures, including measures of self-management, quality of care, demographic and clinical factors, and glycaemic control. The analysis of this longitudinal cohort study is described in section 8.6. The last section contains information about the ethics application and approval.

8.2 Hypotheses

There was limited evidence from a systematic review performed by the author of this Thesis and discussed in Chapter 6, that self-management and quality of care are independently associated with glycaemic control. The core research question of this Thesis is ‘What is the relative importance of self-management and quality of care in the prediction of glycaemic control at six-month follow-up?’

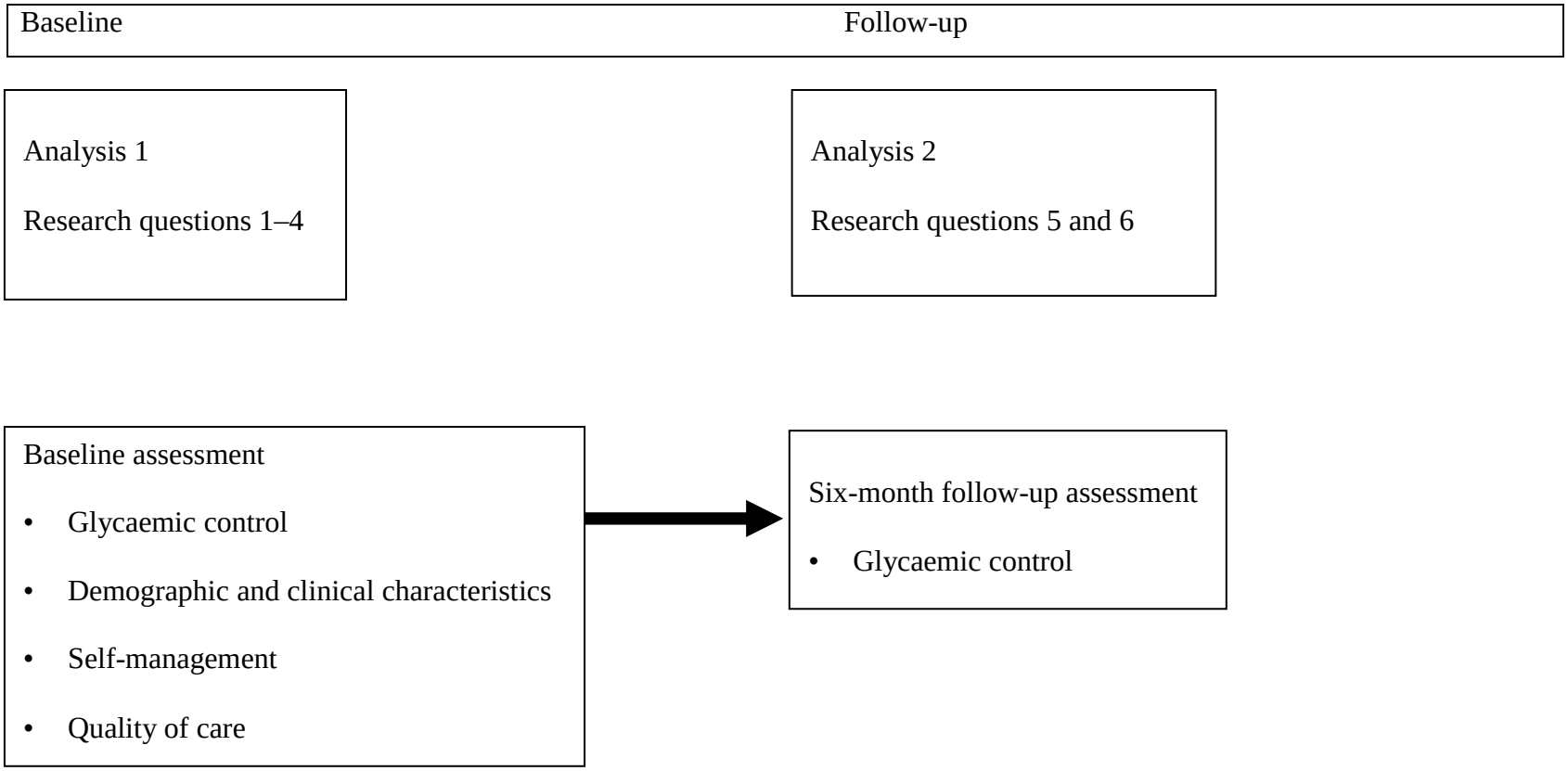
8.3 Study design: Longitudinal cohort study

This study uses a longitudinal cohort design to ascertain the individual contribution of self-management and quality of care and their relative importance as predictors of glycaemic control in patients with type 2 diabetes under the care of the MISS (Figure 8.1). A cohort study is an appropriate design to evaluate both the individual contribution and relative importance because it allows assessment of whether a factor (measured at baseline) is associated with an outcome (measured at least twice – baseline and follow-up) (Altman 1991; Bland 2000). However, cohort studies might be affected by confounders. A confounder is a variable that is not of direct interest in the study, but

which is associated with both the outcome variable and the independent variable (Ajetunmobi 2002; Bland 2000). The strategy used in this Thesis was statistical modelling.

Consecutive patients were recruited from the waiting rooms in primary care practices from December 2009 to April 2010. Predictors of glycaemic control were measured from medical records and interviews with patients at baseline. Glycaemic control (HbA1c) was measured at two time points: baseline and six-month follow-up. The schedule showing the stages of the research project is shown in Appendix 8.1 (p. 315).

Figure 8.1 Study design



8.4 Study population

8.4.1 Context

The study population involves patients with type 2 diabetes under the care of MISS in the city of Aguascalientes. The study population came from five MISS practices that provided care for people living in this city (see Appendix 8.2, p.317). Every practice has an original number (e.g. Practice Nº1) given by MISS. The practices included in this study are located in the city of Aguascalientes but the county (Aguascalientes) has more practices located in rural areas (practices Nº2–6). I only included practices Nº1, 7, 8, 9, and 10 that are located in the city of Aguascalientes. There is a new practice in the city (Practice Nº11) which was opened recently (in 2012). This practice was not included in the Thesis because data collection finished in 2010. There is information about the city of Aguascalientes (geography, demography, and health) in Chapters 2 and 3.

8.4.2 Inclusion criteria

The study included patients with type 2 diabetes and the following characteristics:

- adults (≥40 years old)
- diagnosed with type 2 diabetes ≥1 year prior to commencement of the study
- under consecutive MISS care ≥1 year
- current receiving a monthly prescription of oral glucose-lowering medications
- no insulin prescription

Adults aged 40 or more years were selected according to the International Diabetes Federation finding that type 2 diabetes is usually diagnosed at this age (IDF 2011e). The sample was restricted to patients prescribed oral glucose-lowering medications on an ongoing monthly basis as maintenance therapy, to allow the use of treatment intensification as a measure of quality of care. Patients without medications and under lifestyle interventions (i.e. diet and exercise) might not need to take any medication during the study period. Therefore, these patients were not included because treatment intensification might not be relevant. The MISS practice guideline recommends prescribing insulin when the combination of oral glucose-lowering medications has failed to achieve good glycaemic control (IMSS 2008). Therefore, it was expected that

patients under insulin treatment would not receive treatment intensification and these patients were not included.

There is no system of repeat prescriptions in MISS. Instead, patients with type 2 diabetes are seen by GPs on a monthly basis as part of the care provided to patients with long-term conditions by MISS. It is expected that GPs prescribe treatment based on clinical guidelines. GPs also examine patients' weight and blood pressure, and perform additional examinations (including laboratory evaluations) when patients have more than one condition. This information is recorded in their medical records.

The MISS clinical guideline includes an algorithm (Appendix 8.3, pp. 318-319) about the prescription of glucose-lowering medications for patients with type 2 diabetes under primary care (IMSS 2008). This algorithm suggests prescribing oral glucose-lowering medications when patients continue to demonstrate HbA1c >7% or FBG >130 mg/dl after trying non-pharmacological treatment (i.e. diet and exercise). GPs can start prescribing metformin (to patients with normal weight or who are overweight) or sulfonylurea (to patients under their recommended weight). If FBG does not decrease after eight weeks (patients treated with sulfonylurea) or twelve weeks (patients treated with metformin), GPs can initiate additional medications. If FBG does not decrease after adding more medications, the algorithm suggests prescribing insulin (either alone or with other medications) or prescribing three oral glucose-lowering medications.

The MISS clinical guideline has been updated, but I use the clinical guideline released in 2008 because data collection started in December 2009. The MISS clinical guideline has been updated in 2010 and 2012. The major changes in the guideline were:

- The scope of management and treatment of diabetic neuropathy
- The inclusion of vaccinations (influenza and pneumococcal vaccinations)
- Management of sickness absence
- Changes in medical treatment and glycaemic control
- The inclusion of additional algorithms (i.e. hypoglycaemia management) and appendices (i.e. glycaemic index)

Changes to Medical treatment and glycaemic control are relevant for this Thesis. Maximum metformin dose is 2550mg per day but the guidelines in 2010 and 2012

recommend that the effective maximum dose is 2000mg per day. Both guidelines 2010 and 2012 include more information about effects and combinations of oral glucose-lowering medications.

The prescription of diabetes medications is included in these algorithms and these have changed in the guideline updates. The algorithm included in 2008 recommended to start diabetes management with diet, exercise and self-management and to continue with metformin (in patients with normal weight or who are overweight) or sulfonylurea (in patients under their recommended weight) when patients had HbAlc >7% or FBG >130mg/dl. If patients continued with these glucose levels, the next step was to prescribe combination therapy with metformin and sulfonylurea. Finally, the maximum therapy would include three oral glucose-lowering medications or one oral glucose-lowering medication plus insulin or two oral glucose-lowering medications plus insulin.

The algorithm in 2010 started diabetes management including diet, exercise and self-management (non-medical treatment) plus metformin. The next step was to start combination therapy including metformin plus one oral glucose-lowering medication or metformin plus insulin. Finally, the maximum therapy would include three oral glucose-lowering medication or two oral glucose-lowering medication plus insulin.

The most recent update in 2012 recommends to start diabetes management with non-medical treatment plus metformin or to change metformin for other oral glucose-lowering medication in case of the patient who does not tolerate metformin or in whom it is contraindicated. The next step and the maximum therapy is the same as the update in 2010.

Judgements of treatment intensification would be affected if evaluated using the updated guidelines because the guidelines do not include patient weight anymore.

Glycaemic control based on HbA1c levels was specific in 2008 (HbA1c <7%) but the guideline in 2010 included 2 recommendations (HbA1c <7% or HbA1c <6.5%) and the guideline in 2012 includes recommendations from different diabetes organisations, like the International Diabetes Federation and the American Diabetes Association, ranging from HbA1c <6.5% to HbA1c <7%. The most recent guideline also suggests that

glycaemic control should be individualised but these recommendations are not appropriate for children and pregnant women.

8.4.3 Exclusion criteria

- terminal illness
- any severe mental illness that limits patients' ability to answer questionnaires

8.4.4 Sample size and power

The core research question of the Thesis is 'What is the relative importance of self-management and quality of care in the prediction of glycaemic control at six-month follow-up in primary care?' The sample size calculation was designed to estimate the sample size needed to adequately answer this question and is based on testing for the equality of two dependent correlations (Steiger 1980): between HbA1c and self-management and HbA1c and quality of care. In other words, do measures of self-management and measures of quality of care correlate equally with HbA1c?

Assuming a correlation between self-management and quality of care of 0.1, an intra-cluster correlation of 0.1 [recognising that outcomes of patients at the same practice may not be independent, given that they consult the same GP(s)] and 20% loss to follow-up at six months, a sample of 405 patients would enable a difference as small as 0.2 (e.g. 0.25 vs. 0.05) to be detected between the correlations of HbA1c/self-management and HbA1c/quality of care with approximately 75% power at the 5% level of significance (Faul et al. 2009; Steiger 1980).

8.4.5 Sampling

There are two methods of sampling: probability and non-probability. Probability sampling reduces selection bias because this method 'guarantees that each of the candidates for inclusion in the study has an equal opportunity for selection' (Lunsford and Lunsford 1995, p. 108) and the sample is representative of the population of interest (Altman 1991; Bland 2000). However, probability sampling requires more time and resources to make the necessary arrangements to obtain the sample. Non-probability sampling is often used when studies have time and economic constraints. The drawback

of non-probability sampling is that 'all members of the population do not have an equal chance of being selected' (Lunsford and Lunsford 1995, pp. 109–110). This unequal chance of selection makes it more difficult to generalise results (Lunsford and Lunsford 1995) because the sample is less likely to represent the whole population (Levy and Lemeshow 2008). In Chapter 6, probability sampling was one of the criteria to evaluate the quality of observational studies.

Given the time and financial constraints of the study, it was decided that 80% of patients would be selected using non-probability sampling (consecutive recruitment of appointment attendees). A separate random sample (the remaining 20% of the final sample) was drawn and used to evaluate whether the consecutive sample was representative (i.e. whether it suffered from selection bias). The random sample included patients who did not regularly attend their practice. In the main analysis of all patients, any differences between the two samples were adjusted for statistically.

The total planned sample size including consecutive and random sampling was 405 patients. To achieve the required sample size, two patients were to be sampled from each of the 162 GPs across the five practices (324 patients) using consecutive sampling. That is, all eligible patients attending an appointment would be approached, whilst the researcher was present in the practice. The remaining 81 patients were selected at random, one each from half of the GPs (chosen at random).

The consecutive sample included all patients meeting the inclusion criteria within any practice from both morning and afternoon sessions. Patients were approached consecutively on the day that the researcher (the author of this Thesis and a research assistant) was present in the practice (December 2009 to April 2010). GPs were distributed across five general practices. Every practice had from 20 to 40 GPs (see Appendix 8.2, p. 317).

The random sample involved half of the GPs from every practice and one patient per GP (sample size 81 patients). GPs and patients were selected randomly by YM using random number lists generated in Epi Info software (CDC 2001). Recruitment of the random sample was performed using two methods: 1) approaching randomly sampled patients when they visited the practice for diabetes control, and 2) approaching patients

in their homes. The travel expenses to recruit these patients (average of an hour and £3 per patient) were covered by the author.

8.5 Data collection

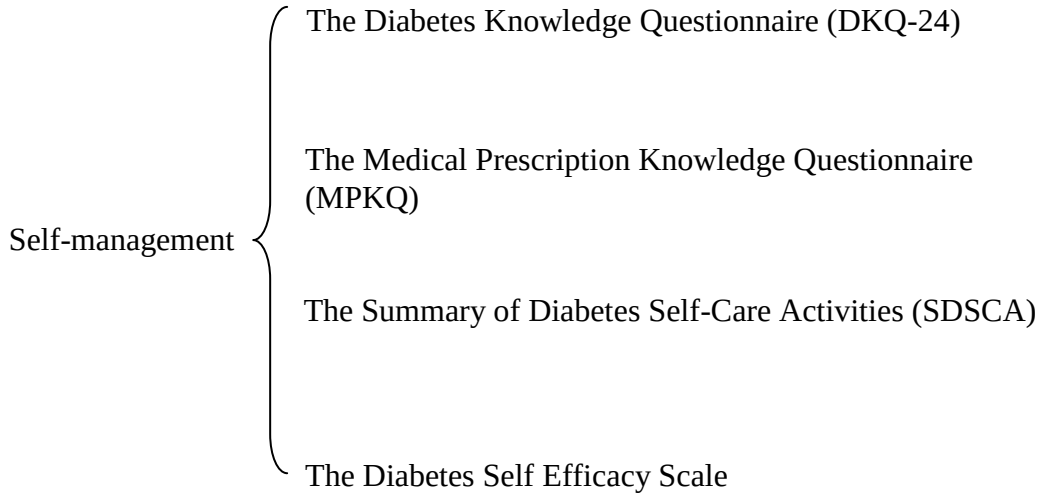
Appendix 8.4 includes the questionnaires and extraction forms used in the study in both English and Spanish (p. 320-389). The questionnaires and forms were presented in a single document divided into six sections. The author of this Thesis translated sections I, II, III, V, and VI. Sections II and IV were available in both English and Spanish from the original studies.

Sections of questionnaires and forms
I) Demographic and clinical characteristics
II) Self-management questionnaires
III) Quality of care questionnaires
IV) Beck Depression Inventory
V) Extracted information from electronic medical records to evaluate patients' medical prescription knowledge, continuity of care, and treatment intensification
VI) Information from laboratory evaluation-blood test to register information about patients' levels of HbA1c, FBG, cholesterol, and triglycerides

8.5.1 Measures of self-management

I assessed diabetes knowledge, diabetes self-management behaviours, and self-efficacy as elements of diabetes self-management, as defined in Chapter 5. Figure 8.2 shows the instruments used in this study.

Figure 8.2 Measures of self-management



8.5.1.1 The Diabetes Knowledge Questionnaire (DKQ-24)

The DKQ-24 measures general diabetes knowledge through 24 items (Garcia et al. 2001). The first three items are shown as examples:

Eating too much sugar and other sweet foods is a cause of diabetes

The usual cause of diabetes is lack of effective insulin in the body

Diabetes is caused by failure of the kidneys to keep sugar out of the urine

The DKQ-24 has three response choices: 1) 'Yes', 2) 'No', and 3) 'I do not know'. 'Yes' or 'No' is the 'correct' response dependent on the question being posed. 'I do not know' is assumed to be incorrect as the patient is not knowledgeable. The total score is calculated based on the sum of correct answers out of a maximum score of 24. This questionnaire is a shortened version of the DKQ-60 which was developed in English and Spanish and tested in a sample of Mexican Americans with type 2 diabetes (Garcia et al. 2001). The authors found high internal consistency for the DKQ-24 (Cronbach's coefficient α 0.78 – it is suggested that Cronbach's coefficient α should be above 0.70 (Nunnally 1978)). The 'level of difficulty' of the DKQ-24 was evaluated with the percentage of participants who answered every item correctly before participating in diabetes education. The percentages of participants answering correctly every item ranged from 14% to 96% and the average was 57% (Garcia et al. 2001). Thorndike and Hagen (1977) suggest that it is expected for new topic tests to find low scores and for well known topics high scores. Although Garcia et al. (2001) evaluated 'level of difficulty' before patients participation in diabetes education, some patients could have scored high because their previous diabetes knowledge. Item discrimination was confirmed with the item-total correlation method. Ideally, an item should correlate with the total score above 0.20 (Streiner and Norman 1995). Item-total correlation for DKQ-24 ranged from 0.27 to 0.37 (Garcia et al. 2001). Construct validation was evaluated using the method of differentiation between groups. It was hypothesised that patients participating in diabetes education and support sessions would score higher in the DKQ-24 compared with patients who did not receive this intervention. There is evidence that diabetes knowledge improves after diabetes education (Deakin et al. 2005; Duke et al. 2009). In a 3-month follow-up, the intervention group showed significantly higher

knowledge scores than the control group (15.7, SD 3.4 and 14.3, SD 3.5, respectively, P <0.001) (Garcia et al. 2001).

This questionnaire is included in Appendix 8.4 section II.3 ‘Diabetes Knowledge Questionnaire (DKQ-24)’, p. 334-335.

8.5.1.2 The Medical Prescription Knowledge Questionnaire (MPKQ)

The MPKQ assesses patient knowledge of oral glucose-lowering medications and can be used to classify patients with ‘strong’ or ‘weak’ medical prescription knowledge (Prado-Aguilar et al. 2009). The MPKQ contains three items asking patients for the name of their medication, its dosage, and the dosing interval (open-ended questions), using the following questions:

> *What is the name of the diabetes medication prescribed by your general practitioner?*
>
> *How many times a day do you have to take your medication?*
>
> *How many tablets a day do you have to take each time?*

If patients know their medication name, dosage, and dosing interval, they are classified as having ‘strong’ medical prescription knowledge. However, if patients do not know the answer to at least one question, they are classified as having ‘weak’ medical prescription knowledge. Basically, patients are expected to fully understand all their medications. In an observational study of Mexican patients with type 2 diabetes attending primary care practices, MPKQ was evaluated as a screening test of treatment adherence (Prado-Aguilar et al. 2009) and pill count was used as the gold standard of treatment adherence. Pill count involved two home visits to count: 1) number of pills that patient had in the first visit and 2) number of pills remaining in the second visit. The difference in the number of pills between first and second home visit was divided by the number of pills prescribed for that period (first and second visit) and multiplied by 100. Patients who took between 90 and 105% of pills were classified as having good adherence which was previously recommended by Mason et al. (1995). MPKQ sensitivity and negative predictive value were 68.1% and 82.2%, respectively.

Misclassification was found in less than 20% of nonadherent patients (Prado-Aguilar et al. 2009). Therefore, MPKQ was suggested as a proxy measure of adherence in patients with type 2 diabetes. I did not use the MPK to measure adherence but as a direct measure of medical prescription knowledge.

This questionnaire is included in the Appendix 8.4 section II.2 'Medical Prescription Knowledge Questionnaire', p. 329-333.

8.5.1.3 The Summary of Diabetes Self-Care Activities (SDSCA)

The SDSCA questionnaire measures diabetes self-management including healthy eating, physical activity, monitoring diabetes control (blood glucose testing and foot care), avoiding tobacco, and taking prescribed medications (Toobert et al. 2000). These aspects of self-management are part of the definition of diabetes self-management included in Chapter 5.

The SDSCA contains 12 items. Example items include:

> *How many of the last seven days have you followed a healthful eating plan*?
>
> *On how many of the last seven days did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)*
>
> *On how many of the last seven days did you check your feet?*

The response scale for most of the items refers to the performance of self-management behaviours during the previous seven days (response scale ranges from 0 to 7). An item on smoking asks whether the patient has smoked over the previous seven days ('Yes' or 'No' response choices) and if the answer is 'Yes', there is a linked question asking the average number of cigarettes per day. Higher scores in the SDSCA reflect better diabetes self-management behaviour (Toobert et al. 2000).

The performance of the Spanish version was evaluated using baseline data from two intervention studies of social support for Mexican Americans with type 2 diabetes (Vincent et al. 2008). The SDSCA was administered to participants twice (one week

apart) to determine its accuracy (test-retest reliability). Adequate test-retest reliability coefficient is higher than 0.70 (Streiner and Norman 1995). The Spanish version of the SDSCA showed test-retest coefficients ranging from 0.51 to 1.00. Four items had test-retest coefficients lower than 0.70 (*Following a healthy eating plan, following your eating plan, eating high-fat foods, and participating in at least 30 minutes of physical activity*). Cronbach's coefficient α was 0.71 for all 12 items. Factor analysis was used to assess construct validity of the Spanish version of the SDSCA. Factor analysis identifies items that are correlated and therefore grouped within a factor (Streiner and Norman 1995). Item 4 was eliminated from the analysis (*eating high-fat foods*) because it had the lowest test-retest correlation. Items about foot care and smoking did not load on any of the factors. Nine of the 12 items were correlated into three factors: healthy eating, physical activity, and a factor including both blood glucose testing and taking prescribed medications. These factors explained 61% of the variance. The three-factor solution was conceptually adequate because it included behaviours related to diabetes self-management. This structure was similar to the English version of the SDSCA but there were five factors in the English version: healthy eating, physical activity, blood glucose testing, foot care, and avoiding tobacco (Toobert et al. 2000). Factor analysis was not used in this Thesis because some items were highly inter-correlated (i.e. healthy eating items). This high correlation might be because the wording in the questions was similar (i.e. *how many times in the past week… how many times in the past month*).

For the purpose of this Thesis, the SDSCA was transformed to a total score. This approach identifies the better self-managers in an understandable way, including key self-management behaviours. The total score included four items: following a healthy eating plan (renamed as diet), participating in at least 30 minutes of physical activity (renamed as exercise), foot care, and taking recommended diabetes medications. Smoking was measured in a different response scale and was not included in the total score. Items about self-monitoring of blood glucose were not included because this behaviour was not frequently reported in the sample. The total score was calculated in two steps. The first step involved dichotomising days per week performing self-management behaviours: 0 to 3 days per week and 4 to 7 days per week. Four or more days per week was recommended as a moderate level of adherence (Shaw et al. 2006). The second step was an addition of these behaviours resulting in the number of self-management behaviours performed 4 or more days per week (0–4 behaviours). These

behaviours were dichotomised as 0–2 behaviours performed 4 or more days per week and 3 or 4 behaviours performed 4 or more days per week.

This questionnaire is included in the Appendix 8.4 section II.4 ‘Summary of Diabetes Self-Care Activities (SDSCA)’, p.336-337.

8.5.1.4 The Diabetes Self-Efficacy Scale

The Diabetes Self-Efficacy Scale measures patients’ confidence to perform regularly at the present time behaviours such as healthy eating, physical activity, and problem solving for blood glucose and illness changes (Stanford Patient Education Research Center 2009). Healthy eating and physical activity figured prominently from both Chapter 4 (as part of diabetes management) and from Chapter 5 (as part of diabetes self-management). This scale has eight items. Items related to the three different aspects of diabetes self-efficacy are shown as examples:

> *How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?*
>
> *How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?*
>
> *How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?*

The response scale is numerical ranging from 1 = ‘Not at all confident’ to 10 = ‘Totally confident’. The score for the scale is the mean of the eight items. Higher scores in the Diabetes Self-efficacy Scale reflect better diabetes self-efficacy.

The Diabetes Self-Efficacy Scale was originally developed and tested in Spanish by the Stanford Patient Education Research Centre for use as one of the outcomes of the Diabetes Self-Management Programme (Lorig 1996). Perceived self-efficacy was ‘related to the willingness and the ability of people to engage in various behavioural challenges including preventive and disease management behaviours’ (Anderson et al. 2000, p. 739). The diabetes self-efficacy scale focuses on patient confidence in

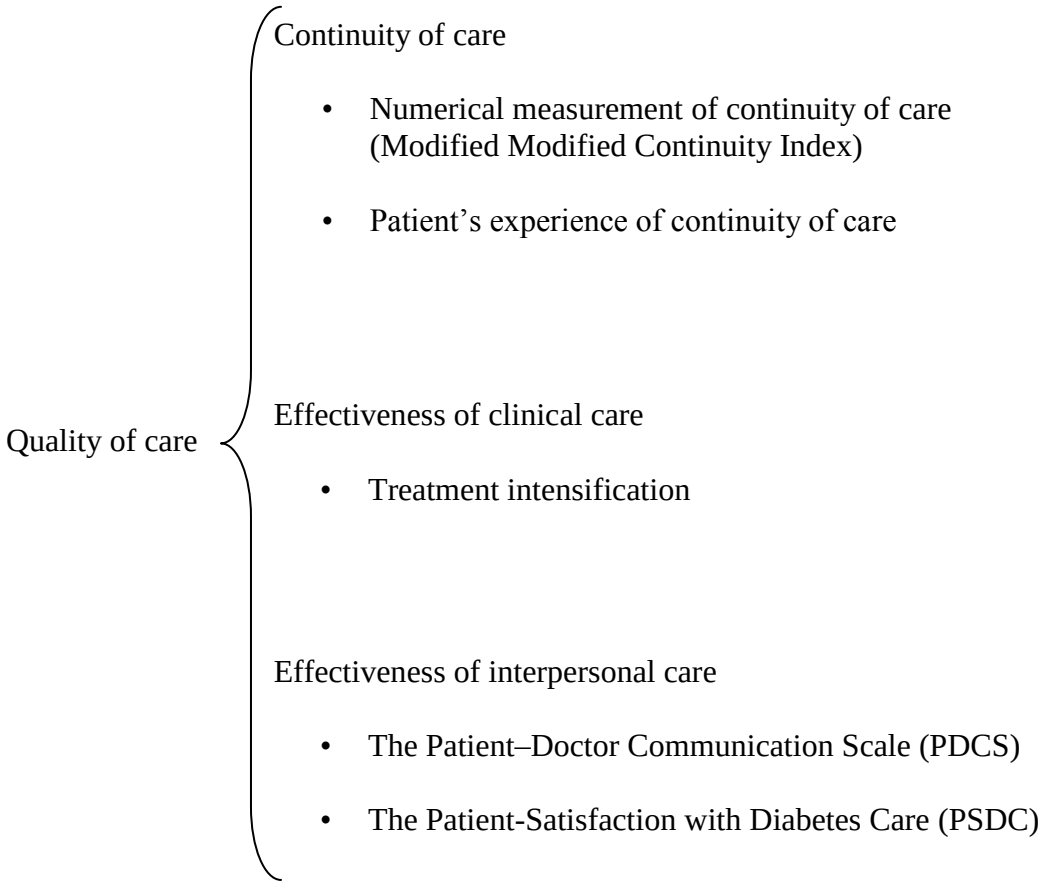
performing diabetes self-management related behaviours. Cronbach's coefficient α was 0.85 and test-retest validity was 0.80 (Lorig et al. 2009).

This questionnaire is included in the Appendix 8.4 section II.1 'Diabetes Self-Efficacy Scale', p.327-328.

8.5.2 Measures of quality of care

I measured dimensions of quality of care defined in Chapter 5: continuity of care, and clinical and interpersonal care based on Campbell et al. (2000). Quality of care measures are summarised in Figure 8.3.

Figure 8.3 Measures of quality of care



8.5.2.1 Continuity of care

The definition of continuity of care is outlined in Chapter 5. I measured the frequency with which patients were seen by their usual GP (relational continuity of care). Although, it is possible to identify long-term relationships between patients and practitioners from medical records, it is not possible to know the nature of this relationship (Saultz 2003) using measures of frequency. I used a numerical measure of continuity of care to evaluate relational continuity without knowing the nature of the relationship between patients and GPs as well as a subjective measure focused on the frequency that patients were seen by their usual GP.

8.5.2.1.1 Numerical measure of continuity of care

The number of encounters between patients and GPs was extracted from electronic medical records by the author and six healthcare students. The extraction included information over a period of six months prior to the recruitment of patients. A modified and validated continuity index was used: the Modified Modified Continuity Index (MMCI) (Magill and Senf 1987) using the following formula:

$$\text{MMCI}=\frac{1-(n\ of\ general\ practitioners/[n\ of\ visits+0.1])}{1-(1/[n\ of\ visits+0.1])}$$

The score ranges from 0 (each visit to a different GP) to 1 (all visits to the same GP).

An extraction form was used to measure continuity of care and it is included in the Appendix 8.4 section V.2 ‘Continuity of care’, p 347.

8.5.2.1.2 Patients’ experience of continuity of care

Patients’ experience of continuity of care was measured with the subscale of continuity of care from the General Practice Assessment Questionnaire (GPAQ) (Mead et al. 2008). The GPAQ was developed to evaluate patients’ perception of quality of care including a subscale of continuity of care. There are other questionnaires that have been developed for the same purpose. For example, the Primary Care Assessment Survey (PCAS) (Benachi Sandoval et al. 2012; Safran et al. 1998), the General Practice

Assessment Survey (GPAS) (Ramsay et al. 2000), and the European Task Force on Patients Evaluations of general Practice (EUROPEP) (Grol et al. 2000). All these questionnaires are valid and reliable but continuity of care is measured differently in every questionnaire, and my aim was to measure the frequency that patients were seen by their usual GP. The PCAS includes a measure of longitudinal continuity (duration of patient's relationship with GP) and visit-based continuity (frequency seeing GP for routine check-ups and for appointments when sick) (Safran et al. 1998). Although the PCAS asks about frequency, the items differentiate between routine and sickness appointments. The GPAQ does not make this distinction and includes all the visits to primary care. The GPAS was a previous version of the GPAQ and therefore I used the most recent version. The EUROPEP does not include a scale measuring continuity of care.

There was not an available Spanish version of the GPAQ but I translated the items into Spanish.

The subscale of continuity of care from the GPAQ contains two items with a specific response scale that were used in this Thesis.

In general, how often do you see your usual doctor?

This item has a response scale ranging from 'never' to 'always' ('never', 'almost never', 'some of the time', 'a lot of time', 'almost always', and 'always'). Higher frequency being seen by the usual GP indicates better continuity of care.

How do you rate this?

This item has a response scale ranging from 'very poor' to 'excellent' ('very poor', 'poor', 'fair', 'good', 'very good', and 'excellent'). Higher rate about the frequency being seen by the usual GP indicates better continuity of care.

Psychometric characteristics of the GPAQ confirmed that the questionnaire is valid and reliable (Mead et al. 2008). GPAQ is a multidimensional questionnaire and the factor analysis showed a structure of three factors: 'access', 'communication', and 'enablement'. Items of continuity of care were related to access and communication

factors from two types of questions: report (frequency seen by a usual GP) and rating (perception of frequency seen by a usual GP). GPAQ showed internal reliability (Cronbach's coefficient α from 0.86 to 0.97). However, continuity of care scale was not evaluated on its internal reliability because it is scored using one item (rating of continuity), and internal reliability refers to the correlation between items in a scale (Streiner and Norman 1995). I used the report question and its correlation with an objective measure was also evaluated. Although using selective items (continuity of care scale) from a questionnaire can decrease validity and reliability, the continuity items from GPAQ are not supposed to be combined with other items to obtain a total score.

The GPAQ was developed to measure quality of care in general practice where GPs are the main providers and gatekeepers to specialist care. The provision of general practice in MISS is by GPs who are also main providers and gatekeepers. This similarity makes it possible to transfer the GPAQ into the Mexican setting.

Items of continuity of care from GPAQ are included in the Appendix 8.4 section III.1 'Continuity of care from GPAQ', p. 338.

8.5.2.3 Treatment intensification

Good glycaemic control reduces the chances of clinical complications associated with type 2 diabetes, the risk of microvascular endpoints, and the risk of myocardial infarction (UKPDS 1998a; UKPDS 1998b). The intensive treatment policy in the United Kingdom Prospective Diabetes Study (UKPDS) involved changes in therapy when hyperglycaemia was present; for example, addition of sulfonylureas, metformin, or insulin. I measured effectiveness of clinical care in terms of treatment intensification by GPs when patients are not under glycaemic control (known as hyperglycaemia). The definition of treatment intensification was:

> '... any one of the following 3 occurrences: (a) an increase in the number of drug classes; (b) an increase in the daily dosage of at least 1 ongoing drug class; or (c) a switch to a medication in a different drug class (Schmittdiel et al. 2008, p 589).'

To evaluate treatment intensification, information was extracted from medical records on the date of recruitment (blood glucose and medical prescription) and two months before recruitment (medical prescription) by the author of this Thesis and six healthcare students. Data extractors were trained in a workshop that included a description of the electronic medical record system, a form to extract data, and practical examples. The extraction was made remotely using three desktops that were connected to the MISS intranet. I performed 50% of data extraction and supervised all data extraction. Data extraction was made twice for every patient by independent extractors. The supervision involved reviewing both extractions. If there was any disagreement, YM performed a third review and corrected the error.

Blood glucose at recruitment was the indicator of whether patients needed treatment intensification and this was evaluated by data extractors and the author of this Thesis based on the MISS clinical practice guideline. Target levels of FBG ≤130mg/dl or HbA1c ≤7.0% are recommended by the MISS clinical practice guideline (IMSS 2008). For patients with FBG >130mg/dl or HbA1c >7.0% data extractors looked to see if there was a record that the patient's GP had initiated treatment intensification by comparing the current prescription (recruitment) with the previous prescription (two months before recruitment). This procedure was based on an algorithm included in the guideline (Appendix 8.3, p. 318). When treatment intensification was needed and it was not found in the medical records, it is possible that GPs did not intensify treatment because the patient did not consent to the intensification, but this would not be recorded routinely.

The extraction form is included in Appendix 8.4 sections V.3 'Treatment intensification' and V.4 'Medical prescription', p. 348-351.

8.5.2.4 The Patient–Doctor Communication Scale (PDCS)

Communication has been suggested as an important element of interpersonal quality of care (Campbell et al. 2000; Institute of Medicine 2006). Questionnaires evaluating quality of care also include communication items (i.e. PCAS, GPAS, GPAQ, and EUROPEP). In general, communication items refer to patients' perception of doctor communication skills and are related to the three-function model of the medical interview including the functions: assessing patients' problems and managing patients'

problems (Cole and Bird 2000). The third communication skill is 'building a relationship' but it is not included in these questionnaires. For example, the PCAS contains communication items asking about patients' problems (i.e. symptoms) and management of these problems (i.e. explanations and instructions). The Patient-Doctor Communication Scale (PDCS) was developed in Spanish in the MISS context based on the three-function model of the medical interview but it has not been published.

The PDCS assesses patient's perceptions of doctor's communication skills. The questionnaire has eight items (Velazquez-Abad 2010). Therefore, it was used to measure patient–doctor communication in this Thesis.

Example items include:

The GP greeted me pleasantly

The GP gave me an explanation about what was happening during the examination

I would recommend this GP to my friends

The response scale ranges from never = 1 to always = 5. Total score is a sum of all items (maximum score is 40). Higher scores show better doctor–patient communication. The PDCS was developed through a literature search (Velazquez-Abad 2010). A focus group of patients with type 2 diabetes confirmed that items were comprehensible and unambiguous. These patients were a sample of Mexicans with type 2 diabetes under the primary care of MISS. Eight of 19 items explained 84% of the variance of the scale in a factor analysis. These items were correlated with the Spanish version of the European Task Force on Patient Evaluations on General Practice Care (EUROPEP) instrument (Grol et al. 2000) which includes similar items to the Patient–Doctor Communication scale. This correlation was used to test criterion validity resulting in Spearman correlation of 0.71. The reliability of the Patient–Doctor Communication scale was 0.90 (Cronbach's alpha).

This questionnaire is included in the Appendix 8.4 section III.2 'Patient–Doctor Communication Scale (PDCS)', p. 339.

8.5.2.5 The Patient Satisfaction with Diabetes Care (PSDC)

The PSDC questionnaire measures patients' satisfaction with diabetes care (Prado-Aguilar 2007). The questionnaire has 11 items asking the frequency that patients experience aspects of diabetes care. Example items include:

> *How often is the sugar in your blood high in the laboratory evaluations?*
>
> *How often does the GP respect your feelings?*
>
> *How often does the GP explain to you everything you have to do to take care of your diabetes?*

Response scale ranges from never = 1 to always = 5. The total score was a sum of items. Higher scores showed better satisfaction with diabetes care. The scale was developed and tested using a sample of Mexican patients with type 2 diabetes under the primary care of MISS (Prado-Aguilar 2007). This scale was validated (content validity) with a focus group of researchers who identified dimensions and items of satisfaction with diabetes care (in general practice) and a focus group of people with type 2 diabetes who confirmed that items were comprehensible and unambiguous. The final items were selected using factor analysis. These items explained 68% of the variance of the scale. Cronbach's coefficient α was 0.74 showing that the scale of satisfaction with diabetes care was reliable (Prado-Aguilar 2007).

The questionnaire is in the Appendix 8.4 section III.3 'Patient Satisfaction with Diabetes Care (PSDC)', p. 340-341.

8.5.3 Demographic and clinical factors

This section described demographic and clinical characteristics that are needed for the testing of four of the six research questions:

8.5.3.1 Demographics

All demographic characteristics were obtained from interviews with patients.

8.5.3.1.1 Age

Patients were asked about their date of birth. Age was calculated from the difference between dates of recruitment and birth (Appendix 8.4 items V.2.a 'Date of last consultation' and I.2.a 'Date of birth', p. 347 and 322) and presented in years.

8.5.3.1.2 Gender

Interviewers filled in the forms writing patients' gender by observation (Appendix 8.4 item 'I.2.b Gender', p. 322).

8.5.3.1.3 Level of education

Level of education was asked based on the Mexican census methodology (INEGI 2011). Interviewers asked patients about their level of education giving the following options: 1) no education, 2) <6 years of education, 3) primary school (6 years of education), 4) secondary school (9 years of education), 5) technician (9 or 12 years of education), 6) high school (12 years of education), 7) undergraduate (17 years of education), and 8) postgraduate (≥18 years of education). This variable was recoded into four categories for analysis, by combing 'no education' and '<6 years of education' into a category 'pre-primary school' and 'technician', 'high school', 'undergraduate', and 'postgraduate' were combined into a single category 'from technician to postgraduate' (Appendix 8.4 section I.2.c 'Level of education', p. 322).

8.5.3.1.4 Marital status

Patients were asked about their marital status according to the following options: married, unmarried but cohabiting, divorced, widow/widower, and single. This variable was dichotomised for analysis into 'with partner' (married and unmarried but cohabiting) and 'without partner' (divorced, widow/widower, and single – Appendix 8.4 item I.2.d 'Marital status', p. 322).

8.5.3.1.5 Occupation

Occupation was also asked based on the Mexican census methodology (INEGI 2011). Patients were asked about their occupation as an open question and interviewers selected an option:

1. *Professional*
2. *Technician*
3. *Teacher*
4. *Professional performer (i.e. singer) including sports professions*
5. *Manager in public sector*
6. *Business man/woman excluding agricultural sector*
7. *Manager, business man/woman in agricultural sector*
8. *Farm manager, foreperson*
9. *Agricultural labourer, farm worker, shepherd*
10. *Machine operator, agricultural sector*
11. *Factory foreperson*
12. *Factory worker*
13. *Factory assistant*
14. *Head of department, office worker, clerk*
15. *Merchant, sales person, shop assistant, sales agent*
16. *Hawker*
17. *Janitor*
18. *Maid*
19. *Driver*
20. *Armed forced/security worker*
21. *Artisan*
22. *Employee*
23. *Homeworker*
24. *Pensioner/retired*
25. *Student*
26. *No work activity*
99. *Not applicable*

Occupation was recoded into ‘patients with a job’ (options 1 to 22) and ‘patients without a job’ (options 23 to 26) and renamed as ‘employment status’.

(Appendix 8.4 section I.2.e ‘Patients’ occupation’ and ‘List of occupations’, p. 322-329).

8.5.3.2 Clinical

Some clinical characteristics were obtained from interviews (diabetes duration, comorbidity, and depression) and others from medical records (body mass index and medical prescriptions) and from blood tests (FBG, cholesterol, and triglycerides).

8.5.3.2.1 Duration of diabetes

Duration of diabetes was obtained from patients' self-report but it was not corroborated by any other source (i.e. medical records). Studies have found agreement between patients' self-report and a criterion standard such as medical records and biometric data (Huerta et al. 2009; Okura et al. 2004; Tisnado et al. 2007). For example, Tisnado et al. (2007) found very good agreement about history of diabetes between patient's self-report and medical record (kappa 0.92). Kappa is a measurement of agreement and it has been suggested that kappa higher than 0.81 is interpreted as 'very good' (Altman 1991).

Patients in this Thesis were asked how many years they had had diabetes (Appendix 8.4 item I.3.a 'How long have you had diabetes?' p. 324). Duration of diabetes is presented in years.

8.5.3.2.2 Comorbidity

Comorbidity was defined in Chapter 4 as having more than one clinical condition. There are several measures of comorbidity but these measures can be classified as condition counts and indexes of condition burden (Huntley et al. 2012). Condition counts can be obtained from medical records or patients' self-reports (Fortin et al. 2010; Huntley et al. 2012). The agreement between medical records and self-reports has been evaluated with kappa coefficients, and these studies have reported kappa from 0.43 to 0.82 (Okura et al. 2004; Horton et al. 2010). Self-reports have some advantages over medical records in terms of easier administration and less cost. Therefore, I used patients' self-report to measure comorbidity as a condition count. Patients were asked whether a doctor had given diagnosis of other conditions and/or diabetes complications. A list of 15 common comorbid conditions of diabetes and four diabetes complications were read to patients and they answered 'yes' or 'no' (Appendix 8.4, section I.5 'Comorbidity', p. 325-326).

8.5.3.2.3 Depression (Beck Depression Inventory)

There is a variety of instruments to measure depression that have been translated into Spanish and used in Mexican populations such as the Beck Depression Inventory (BDI), the Hamilton Depression Rating Scale, and the Zung Self-Rating Depression Scale (Jurado et al. 1998; Ruiz Flores et al. 2007; Salcedo-Rocha et al. 2008). The BDI has been tested to detect depression in patients with diabetes with cut-points from 8 to 16, sensitivity from 0.99 to 0.73, and specificity from 0.52 to 0.93 (Lustman et al. 1997). The BDI has been frequently used in diabetes research and it has been used to detect depression in Mexican patients with type 2 diabetes (Garduño-Espinosa et al. 1998; Steed et al. 2003). Therefore the BDI was used to measure intensity of depression in this Thesis. The BDI has 21 items reflecting a particular symptom of depression. Each item has four statements arranged in increasing severity of the symptom (Beck et al. 1988). An example item with its four statements is:

0. *I do not feel sad*
1. *I feel blue or sad*
2. *I am blue or sad all the time and I can't snap out of it*
3. *I am so sad or unhappy that I can't stand it*

The response scale is from 0 to 3. The total score is the sum of items ranging from 0 to 63. The BDI is classified into four categories: none to minimal depression (<10 points), mild to moderate depression (10–18 points), moderate to severe depression (19–29 points), and severe depression (30–63 points).

Jurado et al. (1998) validated a Spanish version of BDI in three studies including Mexican populations. The first study included people from 15 to 65 years old (n=1508) and it found that the Spanish version was reliable (Cronbach's coefficient α 0.87) and the three-factor structure was the same as the original including negative attitudes toward self, performance impairment, and somatic disturbance (Beck et al. 1988). Concurrent validity was evaluated in the second and third studies. The second study included 120 people with depression aged 17 to 72 years old (previously diagnosed by a psychiatrist) who answered both the BDI and the Zung Self-Rating Depression Scale. The correlation between the BDI and the Zung Self-Rating Depression Scale was

r =0.70, P <0.000. The third study included 546 high school students (15 to 23 years old) and the correlation between the BDI and the Zung Self-Rating Depression Scale was r =0.65, P <0.000. The study of Jurado et al. (1998) concluded that the Spanish version of BDI for Mexicans was valid and reliable.

The items of BDI in this Thesis are included in Appendix 8.4, section IV 'Beck Depression Inventory', p. 342-346.

8.5.3.2.4 Body mass index

Body mass index (BMI) was extracted from medical records (date of recruitment). BMI is calculated by dividing patients' weight (kg) by height squared (m^2) but it was not necessary to calculate BMI because it was already included in the medical records. The extraction was made remotely using three desktops that were connected to the MISS intranet. BMI data extraction and supervision involved the same procedures as treatment intensification. The extraction form is included in the Appendix 8.4 V.3.f 'BMI level', p. 347.

8.5.3.2.5 Medical prescription

A list of antidiabetic medications are included in Chapter 4 (Table 4.1) but there are five antidiabetic medications available in the Mexican Institute for Social Security: glibenclamide, metformin, acarbose, rosiglitazone, and pioglitazone. Medical prescription was extracted from medical records including name of medication, frequency, and dose. Name of medication was used to determine whether the prescription included one medication (monotherapy) and two or more medications (combination therapy). The extraction form is included in the Appendix 8.4 section V.4 'Medical prescription', p. 348. Medical prescription data extraction and supervision involved the same procedures as treatment intensification.

8.5.3.2.6 Laboratory evaluations

At recruitment, patients were asked by the author of this Thesis and a research assistant to attend a blood test within a week at the local hospital (Hospital General de Zona Nº1) to measure HbA1c, FBG, cholesterol, and triglycerides. Levels of FBG, cholesterol, and

triglycerides were given as mg/dl using the method of spectrophotometry (Dimension-AR, Dade Behring). Mexican GPs use milligrams per decilitre (mg/dl) as the unit of measure of these laboratory evaluations and UK GPs use moles per litre (mmol/l). Therefore, both units of measure are presented in the results. Laboratory evaluations are included in Appendix 8.4, section VI 'Information from laboratory evaluation-blood test', p. 355.

8.5.4 Dependent variable: glycaemic control

Glycaemic control was assessed using HbA1c levels collected by a student from laboratory evaluations at baseline and six-month follow-up. The student went to local hospital (Hospital General de Zona Nº1) the day after patients had the laboratory evaluation during the study period. She collected the results from the laboratory and included them in Appendix 8.4, item VI.b 'HbA1c', p. 355.

At least three months of follow-up to detect changes in HbA1c levels was one of the four criteria to evaluate the quality of observational studies in Chapter 6 which was fulfilled in this Thesis because the follow-up was 6 months. HbA1c was measured by high performance liquid chromatography.

8.5.5 Procedures of data collection

Face-to-face interviews were conducted with patients to measure self-management, patient-reported quality of care and patient-reported covariates at baseline. I conducted some interviews. The majority were conducted by research assistants and healthcare students (from the School of Nutrition and Public Health at the Universidad Autónoma de Aguascalientes, and the School of Psychology at the Universidad la Concordia). Interviewers were trained to standardise the recruitment and interview procedures. Training involved two activities: 1) two sessions with interviewers to explain how to use every instrument (2 hours each session), and 2) interviewers piloted questionnaires and extraction of data from medical records to confirm procedures. Piloting has been suggested to identify problems in the administration of the instruments (Ajetunmobi 2002; Greenhalgh 2010). The piloting in this Thesis was useful to clarify questions and extract forms. For example, patients were more familiar with the word 'diet' instead of the phrase 'healthy eating plan'. These questions are included in the SDSCA.

The author of this Thesis and a student reviewed the electronic appointment calendar to identify patients with type 2 diabetes on the day prior to recruitment for every practice. The electronic appointment calendar system does not include a diagnosis. Therefore it was necessary to identify patients aged 40 years or older in whom diabetes diagnosis was identified and inclusion criteria were reviewed. The diagnosis was included in the medical record as 'non-insulin-dependent diabetes mellitus' according to the International Classification of Diseases-10 (WHO 2012a). Patients were recruited when they attended their medical consultation at their general practice. The author of this Thesis, or the research assistant, explained the purpose of the study with a patient information sheet and asked patients to provide written informed consent (Appendix 8.5, p. 390-398). Patients were asked to go to the hospital for a laboratory evaluation of HbA1c, FBG, triglycerides, and cholesterol at baseline and follow-up (6 months). Patients from practice Nº1 attend this laboratory as part of their normal care but patients from other practices do not routinely come to this hospital for check-ups. Therefore, better recruitment was expected from practice Nº1. After the laboratory evaluation, patients were interviewed in their homes (within one week). I met every patient during their laboratory evaluation to arrange a date and time for their home interview.

Data extraction from medical records was the last activity in data collection. Data extraction was double-checked to assure its quality in a third review by the author of this Thesis. However, no formal test of agreement was conducted (e.g. inter-rater reliability). Instead, two data extractors reviewed the same medical record separately. If there were differences between data extractors, a third review was performed and corrections were made.

8.6 Statistical analysis

Summary statistics (mean and standard deviation, median and inter-quartile range, or a frequency distribution, as appropriate) are presented for all variables in Chapter 9 (sections 9.2–9.6). However, I performed the main analyses in this Thesis using correlation or regression modelling (linear, binary logistic, or ordered logistic) in order to determine interrelationships between two or more variables.

This section gives an overview of regression and how it was applied to data analysis in this study.

8.6.1 Regression

Regression techniques are employed when the focus of the analysis is to estimate or predict the relationship between one particular variable of interest (the 'dependent variable') and one or more 'independent variables' (Bland 2000).

Regression analysis can be used to determine how the dependent variable changes when one of the independent variables changes or which independent variable (or set of variables) is most strongly associated with the dependent variable. It can also be used to estimate the relationship between two variables, controlling for one or more other factors (Altman 1991).

There are different types of regression model, but the most common are linear regression, logistic regression, and ordered logistic regression.

Linear regression is used when the dependent variable is a continuous variable (e.g. weight, blood pressure, etc.). Simple linear regression (one independent variable) can be depicted by the equation:

$$y_i = \alpha + \beta x_i + \varepsilon_i \text{ (Dupont 2009, p. 49)}$$

and multiple linear regression (two or more independent variables) by the equation:

$$y_i = \alpha + \beta_1 x_{i1} + \beta_2 x_{i2} + \cdots + \beta_k x_{ik} + \varepsilon_i \text{ (Dupont 2009, p. 97)}$$

Dupont (2009) describes the terms used in the equation as follows (p. 97):

y_i	is the value of the dependent variable for the i^{th} patient
$\alpha, \beta_1, \beta_2, \ldots, \beta_k$	are unknown parameters, to be estimated
$x_{i1}, x_{i2}, \ldots, x_{ik}$	are the values of known variables measured on the i^{th} patient,
$\varepsilon_1, \varepsilon_2, \ldots, \varepsilon_n$	are mutually independent (i.e. ε_i is unaffected by ε_j) errors for the i^{th} 'unit' (e.g. a patient), which are assumed to follow a normal

distribution with mean 0 and standard deviation σ (Dupont 2009, p. 49).

The term 'α' is a constant, corresponding to the estimated value of y_i when all independent variables are set to zero (Altman 1991).

The regression coefficients (β_1, β_2,…, β_k) indicate the predicted increase in γ_i for each unit increase in the corresponding independent variables (x_{i1}, x_{i2},…, x_{ik}), holding all others constant (Altman 1991).

Logistic regression is used when the dependent variable is a binary variable (e.g. Yes/ No). Logistic regression models a transformation of the dependent variable (e.g. the logistic transformation: logit $(p_i) = \log [p_i/(1 - p_i)]$) and estimates the probability that the outcome of the dependent variable will be 'positive' as the independent variables change. As such, the exponential function of the regression coefficients can be considered 'as a measure of the estimated probability, or risk, of' a positive outcome in one group of individuals compared to another group of individuals (Altman 1991, p. 354). Dependent variables, having more than two 'ordered' categories (e.g. Likert scales), should be analysed using ordered logistic regression (Bland 2000), an extension of binary logistic regression.

Table 8.1 includes what type of analysis was used for each variable. Although the primary dependent variable in this Thesis was glycaemic control (HbA1c levels) and the main analysis method was linear regression, other variables were used as outcomes to answer the following two research questions (*RQ2 and RQ3,* included on page 19), and required linear, binary logistic, or ordered logistic regression respectively.

Table 8.1 Type of analysis per variable in the main analysis

Variable	Descriptive	Test
Outcome		
Glycaemic control (HbA1c)	Mean and standard deviation	Simple and multiple linear regressions
Predictors		
Diabetes knowledge	Mean and standard deviation	
Medical prescription knowledge	Frequency and percentage	
Self-management behaviours	Mean and standard deviation Frequency and percentage	
Diabetes self-efficacy	Mean and standard deviation	
Continuity of care (index)	Mean and standard deviation	
Continuity of care (self-report)	Frequency and percentage	
Treatment intensification	Frequency and percentage	
Patient–doctor communication	Mean and standard deviation Frequency and percentage	
Patient satisfaction with diabetes care	Mean and standard deviation	

8.6.2 Independent variables

As noted earlier, independent variables are either continuous or categorical. The impact of a continuous variable, such as age or duration of diabetes, is measured by how much a one-unit change affects the dependent variable. It is common practice to centre a continuous variable at its mean to aid interpretation, whilst also minimising the impact of multi-collinearity (defined in section 8.6.5) when estimating the interaction[1] between two (or more) independent variables (Aiken and West 1991). For categorical variables, e.g. gender (binary); practice (nominal – no obvious order); level of education (ordinal), dummy variables (0/1) are created to compare each category with a 'baseline' (for which all dummies are zero). Omnibus hypothesis tests are then used to test if all parameter estimates are simultaneously zero, providing an 'overall' assessment of the relationship with the dependent variable.

[1] Interaction 'occurs when the relationship between two variables changes markedly when the values of another variable (s) are taken into account'. Cramer, D. & Howitt, D. 2004. The Sage dictionary of statistics: a practical resource for students in the social sciences SAGE.

8.6.3 Choosing a model

Different approaches to choosing a parsimonious regression model have been suggested: forward selection, backward selection, and stepwise selection. Parsimony is an attempt to select a subset of independent variables which most effectively summarises the data (without reproducing it by over-complicating the model).

Forward selection adds the independent variable with the strongest significant association with the dependent variable until no more associations are significant at the chosen level of significance. Backwards selection removes the independent variable with the weakest non-significant association until no associations are non-significant at the chosen level of significance. Stepwise selection is a combination of the above two methods.

I did not search for a parsimonious model. I was less concerned with a parsimonious model, as the research questions were based on a comparison of the individual and relative importance of self-management and quality of care.

8.6.4 Goodness-of-fit of the model

The overall significance of the model in predicting the outcome is determined by an F-test in linear regression and by the chi-squared test in logistic regression and ordered logistic regression. The percentage of variance explained (R^2) by the model can also be calculated, although, in logistic regression, it can only be treated as an approximation. One drawback to this approach is that R^2 is expected to increase simply by adding more variables to the model. To overcome this problem, an adjusted R^2 (adjusted for the number of coefficients estimated) will compensate 'for the expected chance prediction when the null hypothesis is true' (Altman 1991, p. 346). A high adjusted R^2 implies that data are well summarised by the model. In any case, neither tells us anything about the fit for individuals and so we turn to residual analysis and other diagnostics.

8.6.5 Model checking

Collinearity occurs when two or more independent variables are highly correlated. If this is the case, coefficient estimates may change erratically in response to small model changes. Collinearity is often identified through the standard errors of the affected coefficients being 'large', even when the coefficient estimate itself is no different from zero. Some a priori checks (correlations) on variables that were thought to be collinear were carried out, but formal identification was by calculation of variance inflation factors[2] (VIF). As a 'rule of thumb', a VIF >10 suggests collinearity.

Analysis of residuals examines differences between the observed values of the dependent variable and the corresponding value predicted by the regression model (Altman 1991), collectively known as 'fitted' values. In a good fitting model, the residuals should be, ideally, small and normally distributed, with constant standard deviation across the fitted values. The most discernible way to test these assumptions is with a plot of the residuals against the fitted values, which should reveal a random pattern (zero correlation) with no obvious increase or decrease in variation between the residuals across the range of the fitted values. Analysis of residuals also looks for outliers (observations markedly deviated from the regression line) and linearity (no association between residuals and each independent variable).

Some individual values can have an influence on the parameter estimates. The measure of this influence is called the leverage (usually denoted by h_i). Leverage is considered to be large when the estimate is greater than 0.2 (Dupont 2009). Influential points are often observations that have an extreme value on one or more independent variables or have an unusual combination of values. The effect of such points is to force the fitted model close to the observed value of the response leading to a small residual. Leverage points were calculated to identify any influential observation.

It is expected that regression models are homoscedastic. This means that the ε_i of the regression model are assumed to have constant standard deviation (homoscedasticity)

[2] VIF is 'an indicator of the effect the other explanatory variables have on the variance of a regression coefficient of a particular variable, given by the reciprocal of the square of the multiple correlation coefficient of the variable with the remaining variables'. Everitt, B.S. & Skrondal, A. 2010. The Cambridge dictionary of statistics Cambridge University Press.

across all values of the x_i (Dupont 2009). Homoscedasticity can be tested by inspecting the 'fitted values' vs. residuals plot: no obvious pattern of variation across the fitted values should be evident.

8.6.6 Process of analysis

Summary statistics (mean and standard deviation, median and inter-quartile range, or a frequency distribution, as appropriate) are presented for all variables in Chapter 9 (sections 9.2–9.6). However, I performed the main analyses in this Thesis using correlation or regression modelling (linear, binary logistic or ordered logistic) in order to determine interrelationships between two or more variables. The significance level for any test was taken to be 0.05 (Altman 1991; Bland 2000). A P-value between 0.05 and 0.1 can be interpreted as a 'weak' relationship or difference (Bland 2000). 'Weak' relationships are briefly discussed in the results. The analysis was performed in STATA, version 10 (Stata Corporation 2008).

Categorical and dichotomous variables were described with frequency distributions. Continuous variables were described using the mean and standard deviation in normally distributed data and the median and inter-quartile range (the middle 50% of scores in a distribution – 25% to 75%) were used for non-normally distributed data. Table 8.1 shows the main variables (outcome and predictors) and their description as well as the main tests for the outcome.

The analysis of the relationships between self-management and quality of care was undertaken as follows. Continuous variables were analysed using correlation (diabetes knowledge, diabetes self-efficacy, index of continuity of care, and patient satisfaction with diabetes care). Binary variables were used as dependent variables in univariate logistic regressions (medical prescription knowledge, self-management behaviours, treatment intensification, and patient–doctor communication). Self-reported continuity of care was an ordinal variable with four categories and it was used as the dependent variable of univariate ordered logistic regressions.

The dependent variable in the main analysis was HbA1c at six-month follow-up. There are a variety of approaches to analyse the outcome (HbA1c at follow-up) in the published literature. For example, some studies used change in HbA1c as the outcome,

subtracting HbA1c level at baseline from HbA1c at follow-up, such that a negative score represented improvement in glycaemic control over time (O'Connor et al. 2004). Other studies dichotomised glycaemic control as HbA1c levels <7.0 (Schmittdiel et al. 2008). Although, these approaches were not part of the main analysis in this Thesis, they were explored and included as appendices (Appendices 9.8 and 9.9, pp. 409-412).

The approach used in this Thesis analysed HbA1c at follow-up as continuous dependent variable in univariate linear regressions to answer RQ5 (included on page 20).

Two models were fitted to answer RQ6 (included on page 20): a model controlling for HbA1c at baseline and a model without HbA1c at baseline. HbA1c at baseline was also a continuous variable.

First, univariate linear regression models were examined to evaluate the individual contribution of self-management and quality of care to glycaemic control (HbA1c at follow-up as continuous dependent variable). A multivariate model was then fitted to determine their relative importance. The analysis was rerun controlling for HbA1c at baseline (as continuous variable), practice, sampling method, patient demographics (age, gender, marital status, education level, and occupation), and clinical characteristics (duration of diabetes, cholesterol, BMI, hypertension, comorbidities, diabetes complications, depression, and medical prescription). These variables were entered into the model first, followed by self-management and quality of care. Continuous variables were centred at their mean value in order to minimise multicollinearity in the presence of interactions (Aiken and West 1991). Given that independent variables can be measured in different units, the coefficients (β) are standardised to identify which independent variables have a greater effect on the dependent variable. Standardisation shows by how many standard deviations, rather than 'units', the dependent variable changes, per standard deviation increase in the independent variable. By comparing the coefficients associated with self-management and quality of care from univariate and multivariate regressions, it is possible to examine their individual contribution to HbA1c levels, as well as their relative importance.

There were between one and three patients per GP. It was expected that patient responses may not be independent because individual GPs differ in their treatment styles. Regression coefficient standard errors may be underestimated if this

'hierarchical' data structure is ignored. Models were initially fitted taking account of this data structure, but, as the average number of patients per GP was so small, it had no discernible effect. Model parameters are, therefore, presented without this adjustment.

8.6.7 Secondary analysis

In multiple regression, when the effect of one independent variable on the dependent variable varies according to the value or level of a second independent variable, thus an interaction exists (Dupont 2009). The interaction equation is:

$$y = \alpha + \beta(1)X(1) + \beta(2)X(2) + \cdot\beta(3)X(1)X(2)$$

I performed interactions between self-management, quality of care, and HbA1c. The interaction between self-management and quality of care was chosen because it was expected that both variables would interact in the prediction of HbA1c levels.

HbA1c had a skewed distribution. Therefore, bootstrapping, free from parametric assumptions, was used to derive estimates of error variance for tests of statistical significance, using 10,000 bootstrap samples of data from the original dataset (Efron and Tibshirani 1993).

8.7 Ethical approval

Ethical approval was received from the Ethics Committee of Research on Human Beings at the University of Manchester (ref. 09121 on 17th July 2009) and from the Local Health Research Committee Nº101 at the Mexican Institute for Social Security (R-2009-101-12 on 6th August 2009). Appendix 8.6 includes both ethical approvals letters (p. 399-403).

Chapter 9

Results

9.1 Introduction

The results chapter is divided into 13 sections. Section 2 includes a CONSORT diagram to describe sample recruitment and patient flow from selection to follow-up. The next four sections (3–6) present descriptive data on the sample in terms of demographic (section 3), clinical (section 4), self-management (section 5), and quality of care variables (section 6). Sections 3–6 answer the first research question in this Thesis (included on page 19).

Section 7 tests which demographic and clinical characteristics are related to self-management and quality of care answering the second research question (included on page 19).

Section 8 describes the relationship between self-management and quality of care which is related to the third research question (included on page 19).

Predictors of glycaemic control at baseline are described in section 9, answering to the fourth research question (included on page 20).

There is a description of glycaemic control at baseline, follow-up, and change at follow-up in section 10. Section 11 includes the main analysis of predictors of glycaemic control at follow-up and answers to the final two research questions (included on page 20).

Section 12 shows the regression diagnostics. Section 13 includes a secondary analysis of interactions between self-management, quality of care, and HbA1c. The final section is a summary of the key findings and how they relate to the research questions.

9.2 Study design, recruitment, baseline, and follow-up

The study design is shown in Figure 9.1 and patient flow through the study (CONSORT diagram) is shown in Figure 9.2. There were 26851 patients with diabetes who were registered at the MISS practices participating in this study in 2009 (five practices).

Consecutive and random samples were taken from this population. The consecutive sample was taken only from patients attending their practice for their monthly diabetes control appointment, whilst the random sample was taken from all diabetic patients on the practice registers, but, ultimately, comprised both patients attending their practice and patients approached in their homes.

For the consecutive sample, there were 1203 eligible patients who were identified from practice records and who had a medical appointment with their GP; 1089 patients (91%) attended their appointment. Over half of the eligible patients (650, 60%) could not be approached: sometimes there was more than one patient attending their appointment at the same time (which meant that the researcher was unable to approach both and approached the first patient who attended their appointment) and sometimes the patient was seen by the general practitioner earlier than the planned appointment time. Although a quarter of patients who were approached did not want to give reasons for their refusal to participate, reasons cited by those who did included: not having time to attend the laboratory evaluation and interviews, difficulties attending laboratory evaluation either because of distance or mobility difficulties, disagreement between family members about participation, carer responsibilities, planned travel away, illness, and family crises.

Four hundred and thirty nine consecutive patients were approached, of whom 336 agreed to participate in the study. Participants who failed to attend a subsequent laboratory appointment (n=103) were contacted again, but all refused to have another visit and were thus excluded. A further 37 patients were excluded for other reasons, including: incomplete data from medical records to enable evaluation of treatment intensification (n=24), incomplete data from laboratory evaluations (n=5), being on insulin treatment (n=7), and no prescription of oral glucose-lowering medications (n=1).

Eighty two random patients were selected. Home addresses were available for 49 of these patients, and the remaining 33 patients were approached when they attended a medical appointment at the practice. Twenty one of these 33 patients agreed to participate and all of them attended the laboratory and answered the interviews. Twelve patients did not agree to participate and some of the reasons for their refusal to participate were: not having time to attend the laboratory evaluation and interviews, difficulties attending laboratory evaluation either because of distance or mobility

difficulties and one patient said she did not have diabetes. A further 4 patients were excluded because there was incomplete data from medical records to enable evaluation of treatment intensification.

Seventeen of the 49 ‘random’ patients approached at their homes agreed to participate and all of them attended the laboratory and answered the interviews. No contact could be made with 26 patients for one reason or another, including: they were not living at that address anymore; the address was not found; or there was no-one at home at the time of the visit (but the patient information sheet was left explaining the project and asking to contact Yolanda Martinez). Addresses were provided by the Registration and Insurance Validity Department at the Mexican Institute of Social Security but it seems that some of them were not updated. There were six patients who did not agree to participate and some of the reasons for their refusal to participate were: not having time to attend the laboratory evaluation and interviews and difficulties attending laboratory evaluation either because of distance or mobility difficulties. Two patients who agreed to participate were later excluded for other reasons, including: incomplete data from medical records to enable evaluation of treatment intensification (n=1) and incomplete data from laboratory evaluations (n=1).

Loss to follow-up was less than 10% (n=22 out of 227 patients at baseline). Twenty patients did not attend laboratory evaluations at follow-up (15 consecutive patients and 5 random patients [3 approached at medical appointments and 2 approached at home]) and two patients died during follow-up (both consecutive patients). Three of the 205 patients at follow-up did not attend laboratory appointments but provided written evidence of HbA1c, FBG, cholesterol, and triglycerides (all of them were consecutive patients). All the analyses were performed with the final sample of n=205 (who had complete data on all variables). The average time between baseline and follow-up data collection was 5.8 months (SD 0.8, range 3 to 9). Most patients lost at follow-up were unemployed (86%). Their mean HbA1c was 8.08% (ranging from 4.0% to 14.0%). These characteristics were similar to the total sample (72% unemployed; mean HbA1c 7.9%).

Figure 9.1 Study design

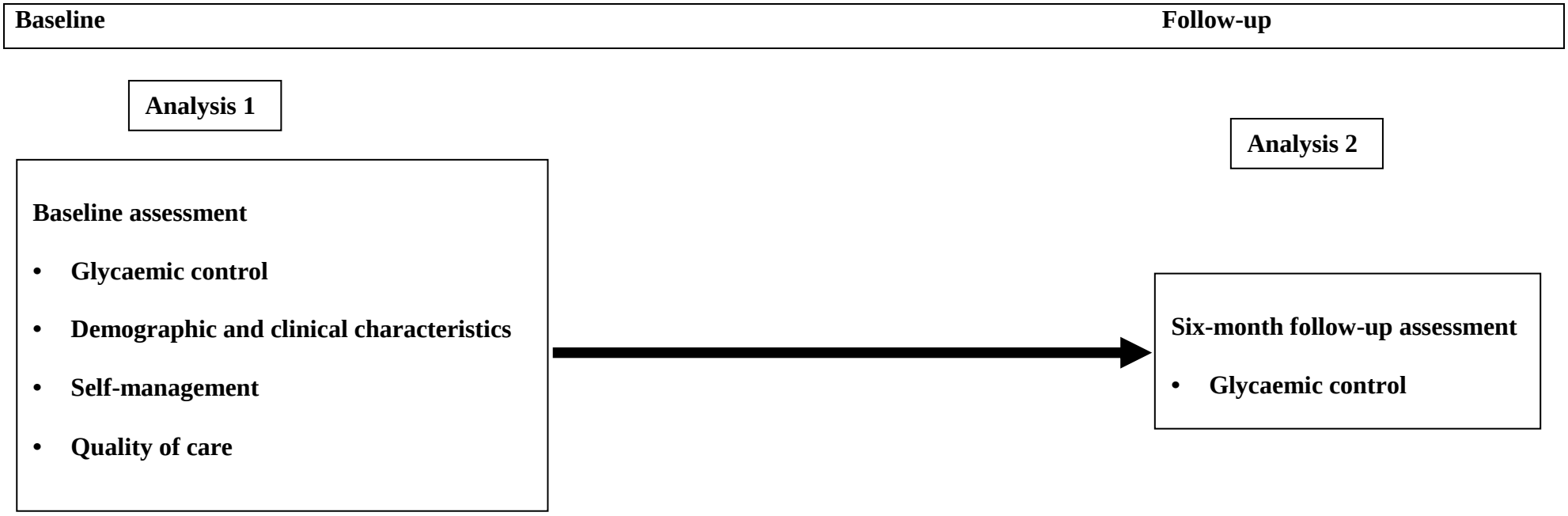
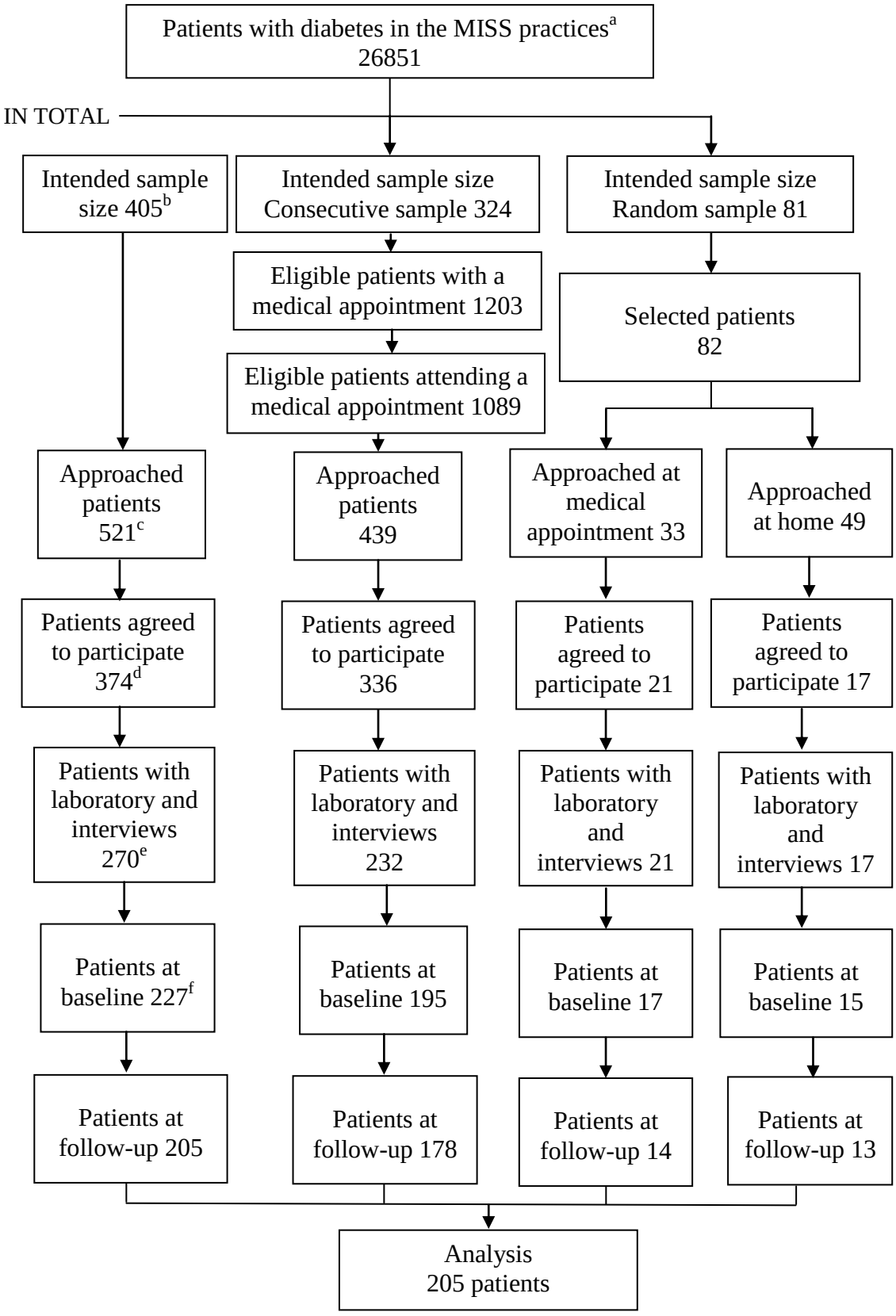


Figure 9.2 CONSORT diagram



Sample size for the analysis was 205 patients. This sample represents: 0.8% of patients with diabetes[a]; 51% of the intended sample[b]; 39% of approached patients[c]; 55% of patients who agreed to participate[d]; 76% of patients with laboratory and interview data[e]; and 90% of patients at baseline.

At baseline, there were 227 patients eligible for follow-up. Loss to follow-up was less than 10% (n=22). Twenty patients did not attend laboratory evaluations at follow-up and two patients died during follow-up. Three of the 205 patients at follow-up did not attend laboratory appointments but provided written evidence of HbA1c, FBG, cholesterol, and triglycerides. All the analyses were performed with the final sample of n=205 (who had complete data on all variables). The average time between baseline and follow-up data collection was 5.8 months (SD 0.8, range 3 to 9).

There was a lack of data on non-respondents (patients refusing to participate and patients who did not attend the lab) because they were not asked for any data. Therefore, at baseline, eligible participants (n=227) were compared with those who were not (n=43). At follow-up, comparisons were performed between those who continued to participate (n=205) and those dropping out (n=22). Data are shown in Tables 9.1 and 9.2.

There was only one variable that was significantly different between included and excluded patients at baseline. Table 9.1 shows that median triglycerides at baseline was significantly higher in excluded patients (241 mg/dl, 2.7 mmol/l) compared to included patients (194 mg/dl, 2.2 mmol/l). Patients with diabetes and high triglycerides (>150 mg/dl, >1.7 mmol/l) have a higher risk of cardiovascular disease (i.e. myocardial infarction and stroke). There was also weak evidence ($p<0.1$) of a difference between included and excluded patients at baseline in other variables. Mean age was higher in included patients (60.8 vs. 58.1; P 0.10). There were more females among included patients (63% vs. 48.8%; P 0.09). Mean FBG was lower in included than excluded patients (163 mg/dl vs. 184 mg/dl, 9.1 mmol/l vs. 10.2 mmol/l; P 0.07). There were fewer patients with normal weight in included than excluded patients (12.8% vs. 25.6%; P 0.07). Mean of diabetes knowledge was lower in included patients (15.7 vs. 16.8; P 0.07). There were fewer patients reporting seen some of the time or less frequently by their usual GP amongst those who were included (14.1% vs. 27.9%; P 0.09).

Table 9.1 Patients at baseline

Variables	Included patients (n=227)	Excluded patients (n=43)	P-value
Practice n (%)			
Nº 1	65 (28.6)	6 (14.0)	P 0.22*
Nº 7	34 (15.0)	8 (18.6)	
Nº 8	59 (26.0)	17 (39.5)	
Nº 9	21 (9.3)	4 (9.3)	
Nº 10	48 (21.1)	8 (18.6)	
Sampling n (%)			
Consecutive	195 (85.9)	37 (86.0)	P 0.59*
Random	32 (14.1)	6 (14.0)	
Demographic			
Age, mean (SD)	60.8 (10.2)	58.09 (9.5)	P 0.10†
Gender, n (%)			
Male	84 (37.0)	22 (51.2)	P 0.09*
Female	143 (63.0)	21 (48.8)	
Marital status			
With partner	168 (74.0)	35 (81.4)	P 0.34*
Without partner	59 (26.0)	8 (18.6)	
Educational level, n (%)			
Illiterate	21 (9.3)	2 (4.7)	P 0.65*
Semiliterate	57 (25.1)	14 (32.6)	
Primary school	75 (33.0)	15 (34.9)	
Secondary school	33 (14.5)	4 (9.3)	
From technician to postgraduate	41 (18.1)	8 (18.6)	
Employment status, n (%)			
Patients with a job	60 (26.4)	16 (37.2)	P 0.19*
Patients without a job	167 (73.6)	27 (62.8)	
Clinical			
Duration of diabetes, median (IQR)	8 (4 to 14.5)	9 (IQR 6 to 13)	P 0.67‡
HbA1c at baseline, mean (SD)	7.9 (2.1)	8.2 (2.6)	P 0.49†
FBG, mean (SD)	163 mg/dl (68.2) 9.1 mmol/l (3.7)	184 mg/dl (76.2) 10.2mmol/l(4.2)	P 0.07†
Cholesterol, mean (SD)	205 mg/dl(39.4) 5.3 mmol/l (1.0)	214 mg/dl(42.0) 5.5 mmol/l (1.0)	P 0.17†
Triglycerides, median (IQR)	194 mg/dl (143 to 258) 2.2 mmol/l (1.6 to 2.9)	241 mg/dl (167.5 to 315) 2.7 mmol/l (1.9 to 3.5)	P 0.014‡
Body mass index, n (%)			
Normal weight	29 (12.8)	11 (25.6)	P 0.07*
Overweight	105 (46.3)	15 (34.9)	
Obesity	93 (41.0)	17 (39.5)	
Hypertension, n (%)			
No	75 (33.0)	16 (37.2)	P 0.60*
Yes	152 (67.0)	27 (62.8)	
Comorbidities, median (IQR)	2 (1 to 3)	2 (1 to 3)	P 0.51‡
Diabetes complications, median (IQR)	0 (0)	0 (0 to 1)	P 0.23‡

Variables	Included patients (n=227)	Excluded patients (n=43)	P-value
Beck Depression Inventory, n (%)			
None to minimal depression	105 (46.3)	13 (30.2)	P 0.18*
Mild to moderate depression	75 (33.0)	21 (48.8)	
Moderate to severe depression	30 (13.2)	5 (11.6)	
Severe depression	17 (7.5)	4 (9.3)	
Medical prescription, n (%)			
Monotherapy	73 (32.2)	16 (38.1)	P 0.47*
Combination therapy	154 (67.8)	26 (61.9)	
Self-management			
Diabetes knowledge, mean (SD)	15.7 (3.6)	16.8 (3.3)	P 0.07†
Medical prescription knowledge, n (%)			
Weak knowledge	155 (68.3)	30 (69.8)	P 1.0*
Strong knowledge	72 (31.7)	13 (30.2)	
Diabetes self-management behaviours, n (%)			
0–2 behaviours four or more days per week	103 (45.4)	20 (46.5)	P 1.0*
three or four behaviours four or more days per week	124 (54.6)	23 (53.5)	
Diabetes self-efficacy, mean (SD)	7.0 (1.7)	6.8 (1.3)	P 0.51†
Quality of care			
Index of continuity of care, mean (SD)	0.71 (0.24)	0.68 (0.29)	P 0.50†
Continuity of care reported by patients			
Some of the time or less frequent	32 (14.1)	12 (27.9)	P 0.09*
A lot of time	40 (17.6)	4 (9.3)	
Almost always	65 (28.6)	13 (30.2)	
Always	90 (39.6)	14 (32.6)	
Treatment intensification, n (%)			
Inappropriate treatment intensification	94 (41.4)	3 (25.0)	P 0.36*
Appropriate treatment intensification	133 (58.6)	9 (75.0)	
Patient–Doctor Communication scale, median (IQR)	37 (26 to 40)	36 (21 to 40)	P 0.26‡
Patient Satisfaction with Diabetes Care, mean (SD)	36.8 (7.2)	35.9 (9.7)	P 0.58†

SD=standard deviation;IQR=interquartile range;*Chi-Square;†t-test;‡Mann-Whitney U. Notes about incomplete data (excluded patients): six patients without HbA1c; one patient without FBG; one patient without cholesterol; two patients without triglycerides; thirty-one patients without enough information in their medical records to calculate treatment intensification.

There were only three variables that differed significantly between patients remaining at follow-up and those who dropped out. Patients remaining in the analysis (n=205) differed significantly from those dropping out (n=22) in being more likely to perform regular self-management behaviours (57% versus 32%, P 0.04), and reporting higher patient–doctor communication (37 versus 28.5, P 0.01) and satisfaction with diabetes care (37.1 versus 33.3, P 0.017). Patient self-management and patient–doctor communication are strategies to improve diabetes care. It is also expected that effective diabetes care improves glycaemic control and reduces the risk of diabetes complications.

Table 9.2 Patients at follow-up

Variables	Follow-up n=205	Lost at follow-up n=22	P-value
Practice n (%)			
Nº 1	60 (29.3)	5 (22.7)	P 0.78*
Nº 7	32 (15.6)	2 (9.1)	
Nº 8	52 (25.4)	7 (31.8)	
Nº 9	18 (8.8)	3 (13.6)	
Nº 10	43 (21.0)	5 (22.7)	
Sampling n (%)			
Consecutive	178 (86.8)	17 (77.3)	P 0.20*
Random	27 (13.2)	5 (22.7)	
Demographic			
Age, mean (SD)	60.8 (10.3)	60.8 (9.5)	P 0.98†
Gender, n (%)			
Male	77 (37.6)	7 (31.8)	P 0.65*
Female	128 (62.4)	15 (68.2)	
Marital status			
With partner	153 (74.6)	15 (68.2)	P 0.60*
Without partner	52 (25.4)	7 (31.8)	
Educational level, n (%)			
Illiterate	18 (8.8)	3 (13.6)	P 0.34*
Semiliterate	51 (24.9)	6 (27.3)	
Primary school	67 (32.7)	8 (36.4)	
Secondary school	33 (16.1)	0	
From technician to postgraduate	36 (17.6)	5 (22.7)	
Employment status, n (%)			
Patients with a job	57 (27.8)	3 (13.6)	P 0.20*
Patients without a job	148 (72.2)	19 (86.4)	
Clinical			
Duration of diabetes, median (IQR)	8 (4 to 14)	9.2 (3 to 18.5)	P 0.54‡
HbA1c at baseline, mean (SD)	7.9 (2.1)	8.0 (2.1)	P 0.76†
FBG, mean (SD)	163.1mg/dl(69.4) 9.0 mmol/l (3.8)	165.9mg/dl(56.9) 9.2 mmol/l (3.1)	P 0.85†
Cholesterol, mean (SD)	206.4mg/dl(38.3) 5.3 mmol/l (0.9)	194mg/dl (48.6) 5.0 mmol/l (1.2)	P 0.17†
Triglycerides, median (IQR)	192 mg/dl (145.5 to 258.5) 2.1 mmol/l (1.6 to 2.9)	194.5 mg/dl (115.5 to 256.5) 2.1 mmol/l (1.2 to 2.8)	P 0.39‡
Body mass index, n (%)			
Normal weight	25 (12.2)	4 (18.2)	P 0.34*
Overweight	98 (47.8)	7 (31.8)	
Obesity	82 (40.0)	11 (50.0)	
Hypertension, n (%)			
No	66 (32.2)	9 (40.9)	P 0.47*
Yes	139 (67.8)	13 (59.1)	
Comorbidities, median (IQR)	2 (1 to 3)	2 (2 to 3)	P 0.22‡
Diabetes complications, median	0 (0)	0 (0 to 1)	P 0.45‡

Variables	Follow-up n=205	Lost at follow-up n=22	P-value
(IQR)			
Beck Depression Inventory, n (%)			
None to minimal depression	95 (46.3)	10 (45.5)	P 0.32*
Mild to moderate depression	68 (33.2)	7 (31.8)	
Moderate to severe depression	25 (12.2)	5 (22.7)	
Severe depression	17 (8.3)	0	
Medical prescription, n (%)			
Monotherapy	65 (31.7)	8 (36.4)	P 0.63*
Combination therapy	140 (68.3)	14 (63.6)	
Self-management			
Diabetes knowledge, mean (SD)	15.8 (3.6)	15.1 (3.9)	P 0.44†
Medical prescription knowledge, n (%)			
Weak knowledge	140 (68.3)	15 (68.2)	P 1.0*
Strong knowledge	65 (31.7)	7 (31.8)	
Diabetes self-management behaviours, n (%)			
0–2 behaviours four or more days per week	88 (42.9)	15 (68.2)	P 0.04*
three or four behaviours four or more days per week	117 (57.1)	7 (31.8)	
Diabetes self-efficacy, mean (SD)	7.05 (1.7)	7.0 (1.4)	P 0.90†
Quality of care			
Index of continuity of care, mean (SD)	0.72 (0.23)	0.66 (0.32)	P 0.40†
Continuity of care reported by patients			
Some of the time or less frequent	28 (13.7)	4 (18.2)	P 0.79*
A lot of time	35 (17.1)	5 (22.7)	
Almost always	59 (28.8)	6 (27.3)	
Always	83 (40.5)	7 (31.8)	
Treatment intensification, n (%)			
Inappropriate treatment intensification	86 (42.0)	8 (36.4)	P 0.65*
Appropriate treatment intensification	119 (58.0)	14 (63.6)	
Patient–Doctor Communication scale, median (IQR)	37 (27.5 to 40)	28.5 (20 to 37.2)	P 0.01‡
Patient Satisfaction with Diabetes Care, mean (SD)	37.1 (7.0)	33.3 (7.5)	P 0.017†

Distribution of patients by practice and type of sampling are shown in Table 9.3. Every practice has a different number of GPs and patients (see Appendix 8.2, p. 317). Therefore it was expected to have fewer patients from smaller practices. Practices 1, 8, and 10 had 20 or 19 GPs (per morning and afternoon session respectively) while practices 7 and 9 had 12 and 10 GPs respectively and per session. It is likely that there were more participants from practice Nº 1 because the laboratory was located next to this practice. Practice Nº 9 is the furthest practice from the laboratory (around 6 miles) and this might be the reason why there were fewer patients from this practice. The ratio of randomly to consecutively sampled patients was expected to be closer to 20:80 but random selection encountered some difficulties. For example, some patients did not usually attend the practice and they were contacted at home. However, some of them were not at home when interviewers visited them or some addresses were incorrect in the patient records. Random selection would have resulted in a very low recruitment rate in a project selecting all the patients with this method.

Table 9.3 Distribution of patients by practice and type of sampling

Variables	N	%
Practice		
Nº 1	60	29.3
Nº 7	32	15.6
Nº 8	52	25.4
Nº 9	18	8.7
Nº 10	43	21.0
Sampling		
Random	27	13.2
Consecutive	178	86.8

9.3 Demographic characteristics

Demographic characteristics of the sample are shown in Table 9.4. These characteristics were similar to a national sample of patients with diabetes (n=1,450,787) under the care of MISS (Vazquez-Martinez et al. 2006). Percentages of females were similar (56% in the national sample and 62.4% in this sample). In general, it has been suggested that women are more frequent users of healthcare services than men (Bertakis et al. 2000; Glaesmer et al. 2012; Xu and Borders 2003) and this finding was also reported for patients with diabetes (Shalev et al. 2005).

The percentage of patients with secondary school or less education was also similar (90% in the national sample and 82.5% in this sample). In Mexico, this percentage is also similar (70%) in people 40 years and older (INEGI 2012a). Vazquez-Martinez et al. (2006) did not show mean age of patients with diabetes but most of them were 40 years or older (87%). Mean age in this sample was 60.8 years (SD 10.3; range 40 to 88); most of the patients were married (71.7%) and, independently, 72.2% were unemployed (including homeworkers, pensioners, and patients without any work activity).

Table 9.4 Demographic characteristics at baseline

Variables	N	Mean (SD) %
Age		60.8 (SD 10.3)
Gender		
Female	128	62.4%
Male	77	37.6%
Marital status		
Married	147	71.7%
Cohabiting	6	2.9%
Divorced	9	4.4%
Widowed	27	13.2%
Single	16	7.8%
Educational level		
Illiterate	18	8.8%
Semiliterate	51	24.9%
Primary school	67	32.7%
Secondary school	33	16.1%
Technician	16	7.8%
High school	13	6.3%
Undergraduate	6	2.9%
Postgraduate	1	0.5%
Employment status		
Employed	57	27.8%
Unemployed*	148	72.2%

* This category included homeworkers, pensioners, and patients without any work activity.

9.4 Clinical characteristics

Figure 9.3 illustrates the distribution of HbA1c at baseline: the mean was 7.9% with a standard deviation of 2.1%. The range was 4.0–16.5%. The histogram shows significant positive skew (1.27) and, as a result, Figure 9.4 displays a box-plot of HbA1c at baseline. The median level was 7.5%, not too dissimilar to the mean, with an inter-quartile range of 6.4–9.0%. The box-plot reveals eight 'outliers' with high values of HbA1c, ranging from 13.0–16.5%.

Figure 9.3: Histogram of HbA1c at baseline

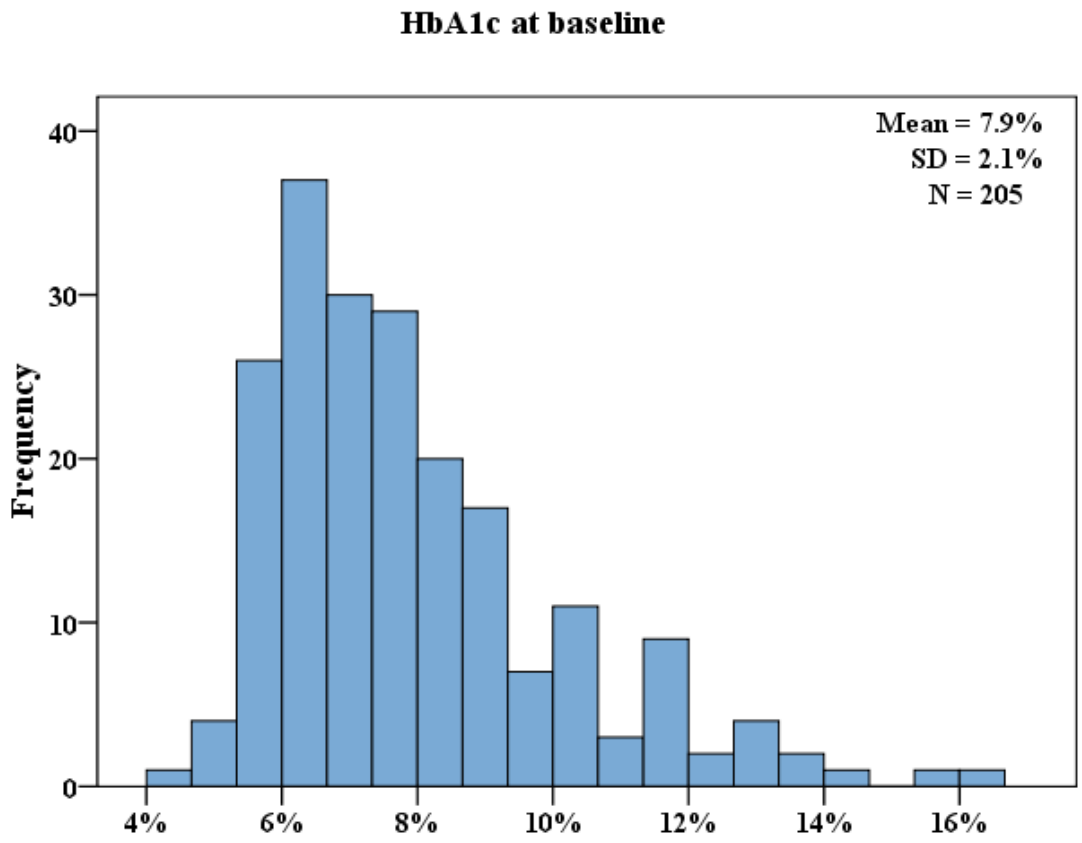
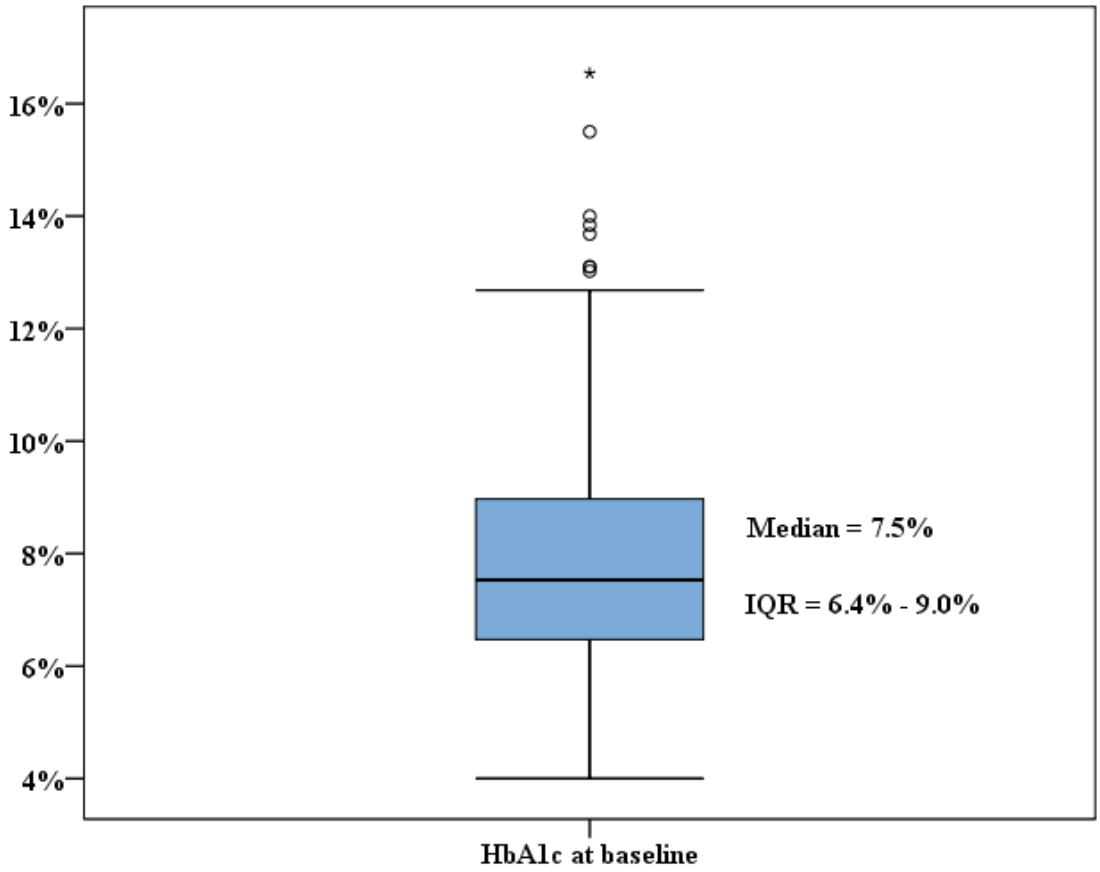


Figure 9.4: Box-plot of HbA1c at baseline



Clinical characteristics of the sample are shown in Table 9.5. More than half of the patients had poor control in terms of FBG (n=129, 63%), cholesterol (n=105, 51%), and triglycerides (n=149, 73%) according to MISS clinical guideline (FBG >130mg/dl, 7.2 mmol/l, cholesterol >200mg/dl, 5.2 mmol/l, and triglycerides >150mg/dl, 1.7 mmol/l). The mean FBG was 163.1mg/dl (SD 69.4; range 55 to 490, 9.1 mmol/l; SD 3.8; range 3.1 to 27.2). The mean cholesterol level was 206.4 mg/dl (SD 38.3; range 121 to 325, 5.3 mmol/l; SD 0.1; range 3.1 to 8.4). The median triglycerides was 192 mg/dl (IQR 146 to 258; range 68 to 1773, 2.2 mmol/l; IQR 1.6 to 2.9; range 0.76 to 19.9).

Patients reported having been diagnosed with diabetes for a median of 8 years (IQR 4 to 14; range 1 to 35). Forty-eight per cent of patients were overweight (BMI 25.0–29.9), whilst 40% were obese. Sixty-eight per cent reported being hypertensive and 54% currently had depression (as assessed by the BDI). More than two-thirds of the patients were prescribed two or more oral glucose-lowering medications (68%).

Table 9.5 Clinical characteristics at baseline

Variables	N	Mean (SD)[§]/ Median(IQR)[‖] %
FBG		163.1 mg/dl (SD 69.4) 9.1 mmol/l (SD 3.8)
Cholesterol		206.4 mg/dl (SD 38.3) 5.3 mmol/l (SD 0.99)
Triglycerides		192 mg/dl (IQR 146–258) 2.2 mmol/l (IQR 1.6–2.9)
Duration of diabetes in years median		8 (IQR 4–14)
Body Mass Index		
Normal (20–24.9 kg/m^2)	25	12.2%
Overweight (25–29.9 kg/m^2)	98	47.8%
Obesity (>30 kg/m^2)	82	40.0%
Patient reported hypertension	139	67.8%
Number of other comorbidities reported by patient*		2 (IQR 1–3)
Number of comorbidities		
0	32	15%
1	65	32%
2	55	27%
3	22	11%
4 ≥	31	15%
Number of diabetes complications reported by patient†		0 (IQR 0–0)
Number of complications		
0	156	76%
1	36	17.5%
2	12	6%
3	1	0.5%
Beck Depression Inventory		10 (IQR 6–17)
Beck Depression Inventory		
None or minimal depression (0–9)	95	46.3%
Mild to moderate depression (10–18)	68	33.2%
Moderate to severe depression (19–29)	25	12.2%
Severe depression (30–63)	17	8.3%
Medical prescription‡		
Monotherapy	65	31.7%
Combination therapy 2	127	62.0%
Combination therapy 3	13	6.3%

* Other comorbidities included: eczema, angina, asthma, arthritis, peptic/stomach ulcer or dyspepsia, gastritis, osteoporosis, heart failure, stroke, urinary incontinence, kidney failure, obesity, and herpes.

† Diabetes complications included retinopathy, nephropathy, neuropathy, and diabetic foot complications.

‡ Combination therapy 2 and 3 referred to medical prescription with 2 and 3 oral glucose-lowering medications, respectively without including insulin therapy.

§ SD = standard deviation

‖ IQR = inter-quartile range

9.5 Self-management characteristics

The self-management characteristics of the sample are shown in Tables 9.6–9.8. On average, respondents scored 66% (16 correct answers out of 24; SD 3.6) on the Diabetes Knowledge Questionnaire. Thirty-one patients (15%) were 'very knowledgeable' scoring ≥20 in the DKQ-24. Most commonly, patients scored 15, 16 or 17 correct answers (n=71; 35%) and 17 patients (8%) were not 'very knowledgeable' scoring ≤10. However, more than two-thirds had 'weak' knowledge about their medical prescriptions (name, dosage, and dosing interval). Patients reported high scores of Diabetes Self-efficacy (mean 7.0, range 2.2 to 10), indicating that, on average, patients were confident in performing self-management behaviours. Foot care and taking recommended medications were the most regularly performed self-management behaviours. Over half of the patients (55%) checked their feet every day and most patients (84%) took their recommended diabetes medications seven days per week. Two self-management behaviours showed poor adherence: participation in specific exercise sessions and self-monitoring of blood glucose. Most patients (87%) did not participate in a specific exercise session and two-thirds did not self-monitor their blood glucose (66%). Table 9.7 shows that there was a fairly uniform distribution across self-management categories for diet-related items and physical activity. Whilst roughly 25% ate healthily and, independently, exercised every day, a similar percentage did so on zero days. Smoking was measured as the percentage of patients who reported smoking in the seven-day prior to the interview. Most patients were not smokers (84%). Table 9.8 shows that over half of the patients (57%) performed three or four self-management behaviours four or more days per week. Histograms and bar charts showing frequency distributions of self-management variables are in Appendices 9.1–9.3 (pp. 404-406).

Table 9.6 Self-management characteristics at baseline

Variables (range)	N	Mean (SD)
Total score of the Diabetes Knowledge Questionnaire (0–24)		15.8 (SD 3.6)
Medical prescription knowledge		
Strong	65	31.7%
Weak	140	68.3%
Total score of the Diabetes Self-efficacy scale (1–10)		7.0 (SD 1.7)

Table 9.7 Summary of Diabetes Self-Care Activities

Self-management behaviour	Median(IQR)	Number of days behaviour was performed			
		0	1–3	4–6	7
		N (%)	N (%)	N (%)	N (%)
Following a healthy eating plan	4 (IQR 1–7)	55 (24%)	49 (22%)	58 (25%)	65 (29%)
Average of days per week in the last month following the eating plan	4 (IQR 3–6)	37 (16%)	42 (19%)	96 (42%)	52 (23%)
Eating five or more fruits or vegetables	3 (IQR 0–6)	69 (30%)	66 (29%)	45 (20%)	47 (21%)
Not eating high fat foods	2 (IQR 1–4)	26 (13%)	125 (61%)	31 (15%)	23 (11%)
Space carbohydrates evenly through the day	5 (IQR 2–7)	45 (20%)	41 (18%)	50 (22%)	91 (40%)
Participating in at least 30 min of physical activity per day	3 (IQR 0–7)	75 (33%)	49 (21.5%)	44 (20%)	58 (25%)*
Participating in a specific exercise session per day	0 (IQR 0–0)	197 (87%)	17 (7%)	1 (0.5%)	11 (5%)*
Self-monitoring of blood glucose	0 (IQR 0–1)	150 (66%)	77 (34%)	—	—
Self-monitoring of blood glucose according to recommendation	0 (IQR 0–0)	159 (70%)	25 (10.5%)	1 (0.5%)	2 (1%)†
Foot care	7 (IQR 3–7)	30 (13%)	48 (21%)	24 (11%)	125 (55%)
Smokers		190 (84%)			
Taking recommended diabetes medications	7 (IQR 7–7)	9 (4%)	6 (2.5%)	21 (9.5%)	191 (84%)

*There was one patient in a wheelchair; †There were 40 patients who did not receive any recommendation from their doctors about self-monitoring of blood glucose

Table 9.8 Total score of the summary of diabetes self-care activities including diet, exercise, foot care, and taking diabetes medications

Number of self-management behaviours performed ≥4 days per week	N	%
0–2 self-management behaviours	88	43%
3–4 self-management behaviours	117	57%

9.6 Quality of care characteristics

Table 9.9 shows the quality of care characteristics of the sample. The item of 'Frequency seeing usual general practitioner' was recoded into four categories: 'some of the time' or less frequently (almost never or never), 'a lot of time', 'almost always', and 'always' because the number of people in some categories was small. There was one patient who selected 'never' and nine patients selected 'almost never'. Eighty-seven per cent self-reported seeing their usual GP 'a lot of the time', 'almost always', and 'always', whilst the objective measure of continuity of care showed that 55 patients (26.8%) had an index value of 1 (the maximum value, indicating that the patient saw the same GP on every visit), whilst 26 patients (12.7%) had an index value <0.5, which can be considered poor continuity (Reilly et al. 2012). The item of 'Rating the frequency seeing usual general practitioner' was also recoded into four categories: 'fair' or less (poor or very poor), 'good', 'very good', and 'excellent' because the number of people in some categories was small. More than three-quarters (78%) rated the frequency of seeing their usual GP as 'good', 'very good', and 'excellent' but only 15.6% rated it as 'excellent'. Eighty patients (39%) had the highest score (40) in the Patient–Doctor Communication scale. The PDCS was dichotomised because of its distribution into 40 and 39 or less. The median total score of the Patient Satisfaction with Diabetes Care questionnaire was 37.1 (SD 7.0; range 20 to 55).

Table 9.10 shows that 25% of patients with high FBG received treatment intensification and that most of the patients under recommended FBG levels continued with the same medical prescription (93%). In total, GPs prescribed medical treatment based on patients' glycaemic control in half of the sample (58%, Table 9.9).

Histograms and bar charts showing frequency distributions of quality of care variables are in Appendices 9.4–9.7 (pp. 407-408).

Table 9.9 Quality of care characteristics at baseline

Variables	N	Mean (SD) Median(IQR) %
Continuity of care from the General Practice Assessment Questionnaire		
Frequency seeing usual general practitioner		
Always	83	40.5%
Almost always	59	28.8%
A lot of time	35	17.0%
Some of the time or less	28	13.7%
Rating the frequency seeing usual general practitioner		
Excellent	32	15.6%
Very good	68	33.2%
Good	59	28.8%
Fair or less	46	22.4%
Index of continuity of care (0–1.0)		0.7 (SD 0.2)
MMCI* =1	55	26.8%
MMCI <0.5	26	12.7%
Appropriate treatment intensification by general practitioner	119	58.1%
Total score of the Patient–Doctor Communication scale (8–40)		37.0 (IQR 27.5 to 40)
Total score of the Patient–Doctor Communication scale = 40	80	39%
Total score of the Patient Satisfaction with Diabetes Care questionnaire (11–55)		37.1 (SD 7.0)

* Modified Modified Continuity Index

Table 9.10 Medical prescription based on patients' glycaemic control

Treatment intensification	Glycaemic control	
	FBG* >130 mg/dl *N* (%)	FBG ≤130 mg/dl *N* (%)
Yes	27 (25%)	7 (7%)
No	79 (75%)	92 (93%)

* FBG = fasting blood glucose (from medical records)

9.7 Relationships between demographic and clinical characteristics and self-management and quality of care

9.7.1 Relationships between demographic and clinical factors and self-management

A point increase in diabetes knowledge means that one more item from the DKQ-24 would be answered correctly (Table 9.11). Diabetes knowledge was significantly higher in younger patients: a 10-year increase in age was associated with a 0.9 point decrease in knowledge (95% CI −1.4 to −0.5, P <0.001). Diabetes knowledge was significantly higher in patients with better education: primary school was associated with a 1.6 point increase in knowledge and secondary school and higher was associated with a 2.4 point increase in knowledge, compared to patients with pre-primary school education. The omnibus test P-value for level of education was <0.001. Diabetes knowledge was significantly higher in patients under combination therapy: combination therapy was associated with 1.1 point increase in knowledge (95% CI 0.04 to 2.17, P 0.040).

'Strong' knowledge about medical prescription was associated with having a better education (Table 9.12). The odds of having 'strong' medical prescription knowledge were over four times greater for patients with a secondary school or higher educational level, compared to pre-primary. However, post-secondary school education did not increase knowledge compared to secondary school education. The omnibus P-value for level of education was 0.005.

Patients were significantly more likely to perform three or four self-management behaviours on four or more days per week if they had a better education or, independently, lower levels of depression (Table 9.13). The odds of performing three or four self-management behaviours was three times greater for patients with post-secondary education compared to pre-primary education, although it was no greater for patients with secondary school education. The omnibus test P-value for level of education was 0.017. The odds of performing three or four self-management behaviours was significantly lower (odds ratio = 0.2) for patients with moderate to severe depression or severe depression, compared to patients with no depression. The omnibus test P-value for depression was 0.003.

Diabetes self-efficacy was significantly higher in patients with higher levels of education (compared to pre-primary), higher cholesterol level, less comorbidity, and less depression (Table 9.14). Self-efficacy was significantly higher in patients with better education: the highest level of education (from technician to postgraduate) was associated with 1.0 point increase in self-efficacy, compared to patients with pre-primary school education. The omnibus test P-value for level of education was 0.029. Self-efficacy was significantly higher in patients with higher cholesterol: a 100 mg increase in cholesterol was associated with 0.8 point increase in self-efficacy, (95% CI 0.2 to 1.0, P 0.006). Self-efficacy was significantly lower in patients with more comorbidities: having 1 further comorbidity was associated with 1.6 point decrease in self-efficacy (95% CI –3.2 to –0.03, P = 0.046). Self-efficacy was significantly lower for patients with moderate to severe depression or severe depression (1.6 and 1.5 points respectively), compared to patients with no depression. The omnibus test P-value for depression was <0.001.

Table 9.11 Univariate linear regressions between demographic and clinical factors and diabetes knowledge

Factors	Unstandardized coefficients	95% confidence intervals	Beta coefficients	P-value
Practice				
Nº 7	0.76	−0.79 to 2.32	0.07	0.388
Nº 8	0.99	−0.35 to 2.34	0.12	
Nº 9	0.18	−1.73 to 2.09	0.01	
Nº 10	−0.32	−1.74 to 1.10	−0.03	
Sampling				
Random	0.60	−0.86 to 2.08	0.05	0.417
Demographic				
Age	−0.09†	−0.14 to −0.05	−0.27†	0.000
Gender				
Female	0.81	−0.21 to 1.83	0.10	0.121
Marital status				
Without partner	0.02	−1.11 to 1.17	0.003	0.960
Educational level				
Primary school	1.59	0.41 to 2.78	0.20	0.001
Secondary school	2.38 †	0.92 to 3.84	0.24 †	
From technician to postgraduate	2.31	0.89 to 3.73	0.24	
Employment status				
Patients without a job	−0.80	−1.91 to 0.30	−0.09	0.154
Clinical				
Duration of diabetes	0.05	−0.01 to 0.12	0.11	0.101
FBG	0.002	−0.004 to 0.01	0.05	0.416
Cholesterol	−0.0008	−0.01 to 0.01	−0.009	0.896
Triglycerides	−0.0002	−0.003 to 0.002	−0.01	0.875
Body mass index				
Overweight	−0.05	−1.65 to 1.55	−0.007	0.985
Obesity	−0.12	−1.76 to 1.51	−0.01	
Hypertension	0.65	−0.41 to 1.71	0.08	0.230
Comorbidities	0.10	−0.22 to 0.43	0.04	0.537
Diabetes complications	0.24	−0.58 to 1.08	0.04	0.557
Beck Depression Inventory				
Mild to moderate depression	0.30	−0.83 to 1.43	0.03	0.372
Moderate to severe depression	1.09	−0.50 to 2.69	0.09	
Severe depression	1.30	−0.57 to 3.17	0.09	
Medical prescription				
Combination therapy	1.11*	0.04 to 2.17	0.14*	0.040

* P-value <0.05; † P-value <0.01

Table 9.12 Univariate logistic regressions between demographic and clinical factors and medical prescription knowledge (0 = 'weak knowledge', 1 = 'strong knowledge')

Factors	Odds ratios	95% confidence intervals	P-value
Practice			
Nº 7	1.44	0.56 to 3.64	0.722
Nº 8	1.58	0.70 to 3.53	
Nº 9	1.75	0.57 to 5.29	
Nº 10	1.06	0.44 to 2.56	
Sampling			
Random	1.31	0.56 to 3.05	0.524
Demographic			
Age	0.97	0.94 to 1.0	0.085
Gender			
Female	1.54	0.82 to 2.88	0.173
Marital status			
Without partner	1.33	0.69 to 2.59	0.387
Educational level			
Primary school	2.75	1.21 to 6.24	0.005
Secondary school	4.39 †	1.71 to 11.25	
From technician to postgraduate	4.21	1.67 to 10.59	
Employment status			
Patients without a job	0.80	0.42 to 1.54	0.519
Clinical			
Duration of diabetes	0.96	0.92 to 1.01	0.148
FBG	0.99	0.99 to 1.00	0.989
Cholesterol	0.99	0.98 to 1.00	0.300
Triglycerides	0.99	0.99 to 1.00	0.433
Body mass index			
Overweight	2.22	0.76 to 6.43	0.315
Obesity	1.75	0.59 to 5.20	
Hypertension	0.99	0.52 to 1.86	0.981
Comorbidities	0.98	0.80 to 1.19	0.842
Diabetes complications	1.0	0.61 to 1.63	0.995
Beck Depression Inventory			
Mild to moderate depression	0.72	0.37 to 1.43	0.828
Moderate to severe depression	0.88	0.34 to 2.26	
Severe depression	0.78	0.25 to 2.41	
Medical prescription			
Combination therapy	0.64	0.34 to 1.18	0.158

† P-value <0.01

Table 9.13 Univariate logistic regressions between demographic and clinical factors and diabetes self-management behaviours (0 = 'less than two behaviours four or more days per week', 1 = 'three or four behaviours four or more days per week')

Factors	Odds ratios	95% confidence intervals	P-value
Practice			
Nº 7	1.12	0.47 to 2.66	0.937
Nº 8	1.4	0.65 to 2.97	
Nº 9	1.09	0.37 to 3.15	
Nº 10	1.21	0.55 to 2.67	
Sampling			
Random	0.93	0.41 to 1.05	0.864
Demographic			
Age	1.02	0.99 to 1.05	0.097
Gender			
Female	0.70	0.39 to 1.25	0.238
Marital status			
Without partner	0.68	0.36 to 1.28	0.234
Educational level			
Primary school	2.21	1.10 to 4.41	0.017
Secondary school	0.96 *	0.41 to 2.21	
From technician to postgraduate	3.0	1.26 to 7.17	
Employment status			
Patients without a job	1.05	0.56 to 1.95	0.867
Clinical			
Duration of diabetes	1.0	0.96 to 1.04	0.770
FBG	0.99	0.99 to 1.0	0.185
Cholesterol	1.0	0.99 to 1.01	0.330
Triglycerides	1.0	0.99 to 1.0	0.443
Body mass index			
Overweight	0.81	0.32 to 2.02	0.501
Obesity	0.62	0.24 to 1.56	
Hypertension	0.80	0.44 to 1.46	0.482
Comorbidities	1.01	0.84 to 1.21	0.885
Diabetes complications	0.68	0.42 to 1.08	0.106
Beck Depression Inventory			
Mild to moderate depression	0.58 †	0.30 to 1.11	0.003
Moderate to severe depression	0.21	0.08 to 0.55	
Severe depression	0.25	0.08 to 0.74	
Medical prescription			
Combination therapy	1.32	0.73 to 2.40	0.348

* P-value <0.05; † P-value <0.01

Table 9.14 Univariate linear regressions between demographic and clinical factors and Diabetes Self-efficacy

Factors	Unstandardized coefficients	95% Confidence Intervals	Beta coefficients	P-value
Practice				
Nº 7	−0.21	−0.97 to 0.54	−0.04	0.222
Nº 8	−0.70	−1.36 to −0.04	−0.17	
Nº 9	−0.76	−1.70 to 0.16	−0.12	
Nº 10	−0.26	−0.96 to 0.42	−0.06	
Sampling				
Random	−0.37	−1.09 to 0.34	−0.07	0.304
Demographic				
Age	0.008	−0.01 to 0.03	0.04	0.488
Gender				
Female	−0.25	−0.75 to 0.24	−0.06	0.319
Marital status				
Without partner	−0.25	−0.81 to 0.30	−0.06	0.370
Educational level				
Primary school	0.52	−0.06 to 1.11	0.14	0.029
Secondary school	0.04 *	−0.68 to 0.77	0.009 *	
From technician to postgraduate	0.97	0.26 to 1.68	0.21	
Employment status				
Patients without a job	−0.02	−0.57 to 0.51	−0.007	0.915
Clinical				
Duration of diabetes	−0.005	−0.03 to 0.02	−0.02	0.767
FBG	−0.002	−0.006 to 0.0006	−0.11	0.114
Cholesterol	0.008†	0.002 to 0.01	0.19†	0.006
Triglycerides	0.0005	−0.0008 to 0.002	0.05	0.435
Body mass index				
Overweight	−0.13	−0.91 to 0.65	−0.03	0.430
Obesity	−0.42	−1.21 to 0.37	−0.11	
Hypertension	−0.17	−0.69 to 0.34	−0.04	0.512
Comorbidities	−0.16*	−0.32 to −0.003	−0.13*	0.046
Diabetes complications	−0.04	−0.44 to 0.36	−0.01	0.847
Beck Depression Inventory				
Mild to moderate depression	−0.57	−1.09 to −0.05	−0.15	0.000
Moderate to severe depression	−1.65 †	−2.39 to −0.91	−0.30 †	
Severe depression	−1.54	−2.41 to −0.67	−0.24	
Medical prescription				
Combination therapy	−0.46	−0.99 to 0.05	−0.12	0.077

* P-value <0.05; † P-value <0.01

9.7.2 Relationships between demographic and clinical factors and quality of care

Overweight patients were more likely to be seen by their usual GP; obese patients, however, were not, compared to patients of normal weight. The omnibus test P-value for BMI was 0.026 (Table 9.15).

General practitioners intensified treatment in patients with higher levels of triglycerides (Table 9.17). The odds of treatment intensification by GPs were 0.99 times greater in patients with higher triglycerides levels (95% CI 0.99 to 0.99; P 0.004).

A point increase in satisfaction with diabetes care means that one more item from the Patient Satisfaction with Diabetes Care (PSDC) scale would indicate greater satisfaction. Lower satisfaction with diabetes care was reported by patients attending practice Nº 8, and higher satisfaction was reported by patients with lower levels of FBG (Table 9.19). Attending practice Nº 8 was significantly associated with a 2.7 point decrease in satisfaction with diabetes care, compared to patients attending practice Nº 1. The omnibus test P-value for practices was P 0.030.

Demographic and clinical factors were not significantly related to the index of continuity of care and Patient–Doctor Communication scale (Tables 9.16 and 9.18).

There were some characteristics that showed a weak relationship with quality of care. Patients were more likely to report being seen more frequently by their usual GP if they did not have a partner. Satisfaction with diabetes care was lower in patients with higher FBG. The index of continuity of care was lower in patients selected by random sampling. General practitioners intensified treatment in patients with higher levels of cholesterol and, independently, with depression. Higher satisfaction with diabetes care was reported by overweight and obese patients.

Table 9.15 Univariate ordered logistic regressions between demographic and clinical factors and self-reported continuity of care (1 = 'some of the time or less frequent', 2 = 'a lot of time', 3 = 'almost always', and 4 = 'always')

Factors	Odds ratios	95% confidence intervals	P-value
Practice			
Nº 7	0.78	0.35 to 1.69	0.427
Nº 8	1.64	0.82 to 3.24	
Nº 9	1.25	0.49 to 3.13	
Nº 10	1.28	0.61 to 2.65	
Sampling			
Random	0.79	0.38 to 1.64	0.529
Demographic			
Age	0.98	0.96 to 1.01	0.386
Gender			
Female	1.05	0.63 to 1.76	0.832
Marital status			
Without partner	0.56	0.31 to 1.01	0.056
Educational level			
Primary school	1.75	0.93 to 3.28	0.296
Secondary school	1.30	0.61 to 2.76	
From technician to postgraduate	1.01	0.49 to 2.07	
Employment status			
Patients without a job	1.40	0.80 to 2.44	0.227
Clinical			
Duration of diabetes	0.99	0.96 to 1.02	0.766
FBG	0.99	0.99 to 1.0	0.743
Cholesterol	1.0	0.99 to 1.0	0.520
Triglycerides	1.0	0.99 to 1.0	0.490
Body mass index			
Overweight	2.32 *	1.03 to 5.21	0.026
Obesity	1.21 *	0.54 to 2.74	
Hypertension	1.05	0.61 to 1.79	0.854
Comorbidities	0.87	0.73 to 1.03	0.115
Diabetes complications	1.20	0.79 to 1.84	0.374
Beck Depression Inventory			
Mild to moderate depression	0.82	0.46 to 1.46	0.851
Moderate to severe depression	0.86	0.39 to 1.90	
Severe depression	1.20	0.46 to 3.12	
Medical prescription			
Combination therapy	1.31	0.76 to 2.26	0.323

* P-value <0.05

Table 9.16 Univariate linear regressions between demographic and clinical factors and objective index of continuity of care

Factors	Unstandardized coefficients	95% confidence intervals	Beta coefficients	P-value
Practice				
Nº 7	0.08	−0.01 to 0.18	0.12	0.550
Nº 8	0.04	−0.03 to 0.13	0.09	
Nº 9	0.01	−0.11 to 0.13	0.01	
Nº 10	0.04	−0.04 to 0.13	0.07	
Sampling				
Random	−0.08	−0.17 to 0.01	−0.11	0.101
Demographic				
Age	−0.00002	−0.003 to 0.003	−0.001	0.988
Gender				
Female	−0.03	−0.10 to 0.02	−0.07	0.265
Marital status				
Without partner	0.02	−0.04 to 0.10	0.04	0.481
Educational level				
Primary school	0.0008	−0.79 to 0.08	0.001	0.613
Secondary school	0.01	−0.08 to 0.11	0.01	
From technician to postgraduate	−0.05	−0.15 to 0.04	−0.08	
Employment status				
Patients without a job	−0.03	−0.10 to 0.04	−0.06	0.386
Clinical				
Duration of diabetes	−0.003	−0.007 to 0.001	−0.09	0.184
FBG	0.0001	−0.0003 to 0.0006	0.04	0.535
Cholesterol	−0.0004	−0.001 to 0.0003	−0.07	0.263
Triglycerides	−0.00005	−0.0002 to 0.0001	−0.04	0.562
Body mass index				
Overweight	−0.01	−0.11 to 0.09	−0.02	0.521
Obesity	−0.04	−0.15 to 0.05	−0.09	
Hypertension	0.005	−0.06 to 0.07	0.01	0.880
Comorbidities	−0.001	−0.02 to 0.02	−0.008	0.903
Diabetes complications	0.02	−0.02 to 0.08	0.06	0.341
Beck Depression Inventory				
Mild to moderate depression	−0.03	−0.11 to 0.03	−0.07	0.766
Moderate to severe depression	−0.03	−0.14 to 0.06	−0.05	
Severe depression	−0.01	−0.13 to 0.11	−0.01	
Medical prescription				
Combination therapy	0.03	−0.03 to 0.10	0.07	0.284

Table 9.17 Univariate logistic regressions between demographic and clinical factors and treatment intensification (0 = 'inappropriate', 1 = 'appropriate')

Factors	Odds ratios	95% confidence intervals	P-value
Practice			
Nº 7	0.96	0.39 to 2.34	0.598
Nº 8	0.57	0.27 to 1.23	
Nº 9	0.57	0.20 to 1.67	
Nº 10	0.80	0.36 to 1.79	
Sampling			
Random	1.08	0.47 to 2.46	0.848
Demographic			
Age	1.01	0.98 to 1.04	0.257
Gender			
Female	0.66	0.37 to 1.19	0.173
Marital status			
Without partner	0.73	0.39 to 1.38	0.342
Educational level			
Primary school	0.84	0.42 to 1.64	0.264
Secondary school	1.42	0.60 to 3.35	
From technician to postgraduate	1.85	0.78 to 4.35	
Employment status			
Patients without a job	1.08	0.58 to 2.0	0.798
Clinical			
Duration of diabetes	0.98	0.94 to 1.02	0.395
Cholesterol	0.99	0.98 to 1.0	0.087
Triglycerides	0.99†	0.99 to 0.99	0.004
Body mass index			
Overweight	0.92	0.37 to 2.31	0.201
Obesity	0.56	0.22 to 1.41	
Hypertension	0.83	0.45 to 1.50	0.543
Comorbidities	1.03	0.85 to 1.23	0.734
Diabetes complications	0.88	0.55 to 1.39	0.594
Beck Depression Inventory			
Mild to moderate depression	0.47	0.25 to 0.90	0.105
Moderate to severe depression	0.46	0.19 to 1.14	
Severe depression	0.72	0.25 to 2.08	

† P-value <0.01. FBG and medical prescription were not included in the clinical factors of treatment intensification because both are involved in the decision of treatment intensification.

Table 9.18 Univariate logistic regressions between demographic and clinical factors and patient–doctor communication (0 = 'total score <40', 1 = 'total score 40')

Factors	Odds ratios	95% confidence intervals	P-value
Practice			
Nº 7	1.14	0.48 to 2.69	0.180
Nº 8	0.46	0.21 to 1.01	
Nº 9	0.43	0.13 to 1.38	
Nº 10	0.67	0.30 to 1.50	
Sampling			
Random	1.08	0.47 to 2.47	0.844
Demographic			
Age	1.0	0.97 to 1.02	0.988
Gender			
Female	1.0	0.56 to 1.79	0.988
Marital status			
Without partner	1.33	0.70 to 2.52	0.374
Educational level			
Primary school	1.34	0.67 to 2.65	0.667
Secondary school	0.94	0.39 to 2.23	
From technician to postgraduate	0.82	0.35 to 1.92	
Employment status			
Patients without a job	0.83	0.44 to 1.55	0.575
Clinical			
Duration of diabetes	0.98	0.95 to 1.02	0.612
FBG	0.99	0.99 to 1.0	0.536
Cholesterol	0.99	0.99 to 1.0	0.831
Triglycerides	0.99	0.99 to 1.0	0.943
Body mass index			
Overweight	1.27	0.51 to 3.17	0.731
Obesity	1.02	0.40 to 2.60	
Hypertension	1.58	0.85 to 2.93	0.146
Comorbidities	0.88	0.73 to 1.07	0.209
Diabetes complications	0.71	0.43 to 1.17	0.186
Beck Depression Inventory			
Mild to moderate depression	0.61	0.32 to 1.17	0.382
Moderate to severe depression	0.68	0.27 to 1.69	
Severe depression	0.50	0.16 to 1.54	
Medical prescription			
Combination therapy	0.94	0.51 to 1.71	0.845

Table 9.19 Univariate linear regressions between demographic and clinical factors and patient satisfaction with diabetes care

Factors	Unstandardized coefficients	95% confidence intervals	Beta coefficients	P-value
Practice				
Nº 7	1.83	−1.17 to 4.84	0.09	0.030
Nº 8	−2.73 *	−5.33 to −0.13	−0.16 *	
Nº 9	0.87	−2.82 to 4.56	0.03	
Nº 10	−1.61	−4.36 to 1.12	−0.09	
Sampling				
Random	0.38	−2.50 to 3.28	0.01	0.791
Demographic				
Age	−0.009	−0.10 to 0.08	−0.01	0.849
Gender				
Female	−1.33	−3.34 to 0.67	−0.09	0.193
Marital status				
Without partner	0.78	−1.45 to 3.03	0.04	0.489
Educational level				
Primary school	1.08	−1.32 to 3.49	0.07	0.744
Secondary school	−0.38	−3.35 to 2.58	−0.02	
From technician to postgraduate	0.27	−2.61 to 3.15	0.01	
Employment status				
Patients without a job	0.54	−1.64 to 2.72	0.03	0.625
Clinical				
Duration of diabetes	−0.003	−0.13 to 0.13	−0.003	0.955
FBG	−0.01*	−0.02 to 0.0002	−0.13*	0.053
Cholesterol	−0.005	−0.03 to 0.02	−0.02	0.696
Triglycerides	−0.0007	−0.006 to 0.005	−0.01	0.808
Body mass index				
Overweight	1.60	−1.50 to 4.71	0.11	0.093
Obesity	−0.66	−3.83 to 2.50	−0.04	
Hypertension	−0.80	−2.89 to 1.28	−0.05	0.448
Comorbidities	−0.43	−1.07 to 0.20	−0.09	0.178
Diabetes complications	−0.16	−1.79 to 1.46	−0.01	0.839
Beck Depression Inventory				
Mild to moderate depression	−1.83	−4.04 to 0.37	−0.12	0.265
Moderate to severe depression	−2.03	−5.16 to 1.10	−0.09	
Severe depression	−2.34	−6.01 to 1.32	−0.09	
Medical prescription				
Combination therapy	−0.18	−2.28 to 1.91	−0.01	0.861

* P-value <0.05

9.8 Relationships within and between self-management and quality of care

There were weak but significant relationships within self-management measures, and within quality of care measures, and between self-management and quality of care measures.

Continuous variables (diabetes knowledge, diabetes self-efficacy, index of continuity of care, and patient satisfaction with diabetes care) were analysed using correlations. Binary variables were used as dependent variables in univariate logistic regressions (medical prescription knowledge, self-management behaviours, treatment intensification, and patient–doctor communication). Self-reported continuity of care was an ordinal variable with four categories and it was used as the dependent variable of univariate ordered logistic regressions.

'Strong' knowledge about medical prescription was significantly associated with having higher scores in the Diabetes Knowledge Questionnaire. The odds of having 'strong' medical prescription knowledge were 1.2 times greater for patients with higher scores in the Diabetes Knowledge Questionnaire (OR 1.2, 95% CI 1.09 to 1.33, P <0.001, Table 9.20). Patients were significantly more likely to perform three or four self-management behaviours on four or more days per week if they had higher scores in the Diabetes Self-efficacy scale. The odds of performing three or four self-management behaviours on four or more days per week were 1.5 times greater for patients with higher scores in the Diabetes Self-efficacy scale (OR 1.5, 95% CI 1.23 to 1.75, P <0.001 Table 9.21).

There were significant associations between continuity of care reported by patients (being seen more frequently by the usual GP) and scores on the index of continuity of care, appropriate treatment intensification, scores on the Patient–Doctor Communication scale, and scores on the Patient Satisfaction with Diabetes Care scale (Table 9.22). The odds of being seen by the usual GP were 10.6 times greater when the index of continuity of care was higher (95% CI 3.56 to 31.88, P <0.001). The odds of being seen by the usual GP were 0.5 times greater when treatment intensification was appropriate, compared to inappropriate treatment intensification (95% CI 0.34 to 0.96, P 0.035). The odds of being seen by the usual GP were 2.1 times greater when they scored 40 (the highest score) in the Patient–Doctor Communication scale, compared to patients scoring 39 or less (95% CI 1.25 to 3.59, P 0.005). The odds of being seen by the usual GP were

1.03 times greater for patients with higher scores in the Patient Satisfaction with Diabetes Care scale (95% CI 1.001 to 1.07, P 0.040).

When treatment intensification was the dependent variable in univariate logistic regressions, it was not associated with other self-management and quality of care variables (Table 9.23).

There were significant associations between the Patient–Doctor Communication scale and the Diabetes Self-efficacy scale and the Patient Satisfaction with Diabetes Care scale (Table 9.24). The odds of reporting a total score of 40 in the Patient–Doctor Communication scale were 1.3 times greater for patients with higher scores in the Diabetes Self-efficacy scale (95% CI 1.09 to 1.54, P 0.003). The odds of reporting a total score of 40 in the Patient–Doctor Communication scale were 1.17 times greater for patients with higher scores in the Patient Satisfaction with Diabetes Care scale (95% CI 1.11 to 1.23, P <0.001).

Table 9.25 shows that higher scores in the Patient Satisfaction with Diabetes Care scale were significantly correlated with higher scores in the index of continuity of care ($r = 0.15$, $P < 0.05$).

Table 9.20 Univariate logistic regressions with medical prescription knowledge as the outcome (0 = 'weak knowledge', 1 = 'strong knowledge')

Factors	Odds ratios	95% confidence interval	P-value
Diabetes knowledge	1.20†	1.09 to 1.33	0.000
Diabetes self-management behaviours			
three or four behaviours four or more days per week	1.30	0.71 to 2.38	0.379
Diabetes self-efficacy	1.04	0.88 to 1.23	0.628
Index of continuity of care	0.63	0.18 to 2.16	0.464
Continuity of care reported by patients			
A lot of time	0.61	0.21 to 1.71	0.593
Almost always	0.53	0.21 to 1.37	
Always	0.57	0.23 to 1.39	
Treatment intensification			
Appropriate treatment intensification	1.53	0.83 to 2.82	0.165
Patient–doctor communication			
Total score = 40	1.16	0.64 to 2.12	0.615
Patient's satisfaction with diabetes care	0.97	0.93 to 1.01	0.302

† P-value <0.01

Table 9.21 Univariate logistic regressions with diabetes self-management behaviours as the outcome (0 = 'less than two behaviours four or more days per week', 1 = 'three or four behaviours four or more days per week')

Factors	Odds ratios	95% confidence interval	P-value
Diabetes knowledge	1.06	0.98 to 1.14	0.123
Diabetes self-efficacy	1.47†	1.23 to 1.75	0.000
Index of continuity of care	1.13	0.35 to 3.64	0.837
Continuity of care reported by patients			
A lot of time	1.89	0.67 to 5.29	0.401
Almost always	0.89	0.36 to 2.20	
Always	1.18	0.50 to 2.81	
Treatment intensification			
Appropriate treatment intensification	1.34	0.76–2.35	0.297
Patient–doctor communication			
Total score = 40	1.57	0.88 to 2.79	0.123
Patient's satisfaction with diabetes care	1.03	0.99 to 1.07	0.142

† P-value <0.01

Table 9.22 Univariate ordered logistic regressions with continuity of care reported by patients as the outcome (1 = 'some of the time or less frequent', 2 = 'a lot of time', 3 = 'almost always', and 4 = 'always')

Factors	Odds ratios	95% confidence interval	P-value
Diabetes knowledge	0.96	0.89 to 1.03	0.286
Diabetes self-efficacy	1.0	0.87 to 1.15	0.947
Index of continuity of care	10.6†	3.56 to 31.88	0.000
Treatment intensification			
Appropriate treatment intensification	0.57*	0.34 to 0.96	0.035
Patient–doctor communication			
Total score = 40	2.12†	1.25 to 3.59	0.005
Patient's satisfaction with diabetes care	1.03*	1.001 to 1.07	0.040

* P-value <0.05; † P-value <0.01

Table 9.23 Univariate logistic regressions with treatment intensification as the outcome (0 = 'inappropriate', 1 = 'appropriate')

Factors	Odds ratios	95% confidence interval	P-value
Diabetes knowledge	0.97	0.90 to 1.05	0.532
Diabetes self-efficacy	1.0	0.86 to 1.18	0.913
Index of continuity of care	0.84	0.26 to 2.74	0.780
Patient–doctor communication			
Total score = 40	1.08	0.61 to 1.91	0.783
Patient's satisfaction with diabetes care	1.01	0.97 to 1.05	0.351

Table 9.24 Univariate logistic regressions with patient–doctor communication as the outcome (0 = 'total score <40', 1 = 'total score 40')

Factors	Odds ratios	95% confidence interval	P-value
Diabetes knowledge	1.01	0.93 to 1.09	0.763
Diabetes self-efficacy	1.30†	1.09 to 1.54	0.003
Index of continuity of care	3.38*	0.96 to 11.82	0.056
Patient's satisfaction with diabetes care	1.17†	1.11 to 1.23	0.000

* P-value <0.05; † P-value <0.01

Table 9.25 Pearson correlation coefficients between self-management and quality of care continuous variables

	Diabetes knowledge	Diabetes self-efficacy	Index of continuity of care
Diabetes self-efficacy	−0.01		
Index of continuity of care	0.05	−0.02	
Satisfaction with diabetes care	−0.04	0.10	0.15*

* P-value <0.05

9.9 Factors related to glycaemic control at baseline

Univariate and multiple linear regressions were used to identify factors related to HbA1c at baseline.

In univariate linear regressions, HbA1c was lower in patients attending practice Nº 10; those without a job; those with lower levels of FBG, cholesterol, and triglycerides; those receiving monotherapy of oral glucose-lowering medications; those receiving appropriate treatment intensification; and those scoring high in their satisfaction with diabetes care (Table 9.26).

Attending practice Nº 10 was significantly associated with 1.2% reduction of HbA1c, compared to patients attending practice Nº 1. The omnibus test P-value for practice was P 0.015. A 100 mg increase in FBG was significantly associated with 2% increase of HbA1c (95% CI 1 to 2, P <0.001). A 100 mg increase in cholesterol was significantly associated with 0.8% increase of HbA1c (95% CI 0.1 to 1.0, P 0.025). A 100 mg increase in triglycerides was significantly associated with 0.2% increase of HbA1c (95% CI 0.06 to 0.4, P 0.008). Combination therapy was significantly associated with 1.2% increase of HbA1c, compared to patients with monotherapy (95% CI 0.67 to 1.88, P <0.001). HbA1c was significantly lower (1.5% reduction of HbA1c) in patients receiving appropriate treatment intensification (95% CI −2.05 to −0.94, P <0.001). Increased patient satisfaction with diabetes care was significantly associated with 0.05% reduction of HbA1c (95% CI −0.09 to −0.01; P 0.010).

The multivariate linear regression model, that included all variables, explained 51% of the variation in HbA1c at baseline. Employment, cholesterol, and combination therapy were no longer significant, but practice, FBG, treatment intensification, and patient satisfaction with diabetes care remained so. Attending practice Nº 10 was significantly associated with 1.1% reduction of HbA1c, compared to patients attending practice Nº 1. The omnibus test P-value for practice was P <0.001. A 100 mg increase in FBG was significantly associated with 1% increase of HbA1c (95% CI 1 to 2, P <0.001). HbA1c was significantly lower (0.68% reduction in HbA1c) in patients receiving appropriate treatment intensification (95% CI −1.17 to −0.20, P 0.004). In the univariate analysis, the association between appropriate treatment intensification and HbA1c was stronger (1.5% reduction of HbA1c, 95% CI −2.05 to −0.94, P <0.001). Increased patient

satisfaction with diabetes care was significantly associated with 0.04% reduction in HbA1c (95% CI −0.08 to −0.005; P 0.029).

There were some factors that showed a weak relationship with HbA1c at baseline in the univariate analysis. HbA1c was lower in younger patients, patients without a job, in overweight and obese patients. HbA1c was higher in patients with hypertension. HbA1c was lower in patients with higher score in the satisfaction with diabetes care scale.

Table 9.26 Factors related to HbA1c at baseline

Factors	Univariate analysis				Multivariate analysis			
	Unstandardized coefficients	95% CI	Beta coefficients	P-value	Unstandardized coefficients	95% CI	Beta coefficients	P-Value
Practice								
Nº 7	0.36	−0.53 to 1.26	0.06	0.015	0.20	−0.51 to 0.91	0.03	0.000
Nº 8	−0.13 †	−0.91 to 0.63	−0.02		−0.84 †	−1.4 to −0.23	−0.18	
Nº 9	−0.53	−1.63 to 0.57	−0.07		−1.01	−1.88 to −0.13	−0.13	
Nº 10	−1.17	−1.99 to −0.35	−0.22		−1.14	−1.80 to −0.48	−0.23	
Sampling								
Random	−0.16	−1.02 to 0.70	−0.02	0.713	0.04	−0.59 to 0.68	0.007	0.887
Demographic								
Age	−0.02	−0.05 to 0.003	−0.11	0.087	0.01	−0.01 to 0.04	0.06	0.406
Gender								
Female	−0.03	−0.64 to 0.56	−0.008	0.899	−0.10	−0.63 to 0.42	−0.02	0.704
Marital status								
Without partner	−0.20	−0.88 to 0.46	−0.04	0.546	−0.08	−0.62 to 0.46	−0.01	0.762
Educational level								
Primary school	−0.24	−0.96 to 0.47	−0.05	0.730	−0.43	−1.0 to 0.13	0.11	0.460
Secondary school	0.24	−0.64 to 1.13	0.04		−0.40	−1.16 to 0.35	0.001	
From technician to postgraduate	−0.13	−1.0 to 0.72	−0.02		−0.16	−0.88 to 0.54	0.007	
Employment status								
Patients without a job	−0.63	−1.28 to 0.01	−0.13	0.054	−0.30	−0.89 to 0.29	−0.06	0.317

Factors	Univariate analysis				Multivariate analysis			
	Unstandardized coefficients	95% CI	Beta coefficients	P-value	Unstandardized coefficients	95% CI	Beta coefficients	P-Value
Clinical								
Duration of diabetes	0.02	−0.01 to 0.06	0.09	0.171	0.001	−0.03 to 0.03	0.0005	0.914
FBG	0.02†	0.01 to 0.02	0.67	0.000	0.01†	0.01 to 0.02	0.61	0.000
Cholesterol	0.008*	0.001 to 0.01	0.15	0.025	0.003	−0.002 to 0.009	0.06	0.250
Triglycerides	0.002†	0.0006 to 0.004	0.18	0.008	−0.0007	−0.002 to 0.0006	−0.05	0.301
Body mass index								
Overweight	−0.84	−1.77 to 0.08	−0.19	0.098	−0.09	−0.81 to 0.61	−0.02	0.961
Obesity	−0.30	−1.25 to 0.64	−0.07		−0.06	−0.83 to 0.69	−0.01	
Hypertension	0.56	−0.05 to 1.18	0.12	0.076	0.20	−0.31 to 0.71	0.04	0.439
Comorbidities	−0.03	−0.22 to 0.15	−0.02	0.710	0.0007	−0.15 to 0.15	0.001	0.993
Diabetes complications	0.31	−0.17 to 0.80	0.08	0.203	0.05	−0.31 to 0.43	0.02	0.767
Beck Depression Inventory								
Mild to moderate depression	0.29	−0.36 to 0.96	0.06	0.371	0.32	−0.20 to 0.86	0.07	0.511
Moderate to severe depression	0.76	−0.17 to 1.70	0.11		−0.03	−0.82 to 0.74	−0.01	
Severe depression	−0.14	−1.24 to 0.96	−0.01		−0.14	−1.02 to 0.74	−0.01	
Medical prescription								
Combination therapy	1.27†	0.67 to 1.88	0.28	0.000	0.23	−0.29 to 0.76	0.04	0.386

Factors	Univariate analysis				Multivariate analysis			
	Unstandardized coefficients	**95% CI**	**Beta coefficients**	**P-value**	**Unstandardized coefficients**	**95% CI**	**Beta coefficients**	**P-Value**
Self-management								
Diabetes knowledge	0.05	−0.02 to 0.13	0.09	0.176	0.02	−0.04 to 0.09	0.03	0.419
Medical prescription knowledge								
Strong knowledge	−0.26	−0.89 to 0.36	−0.05	0.407	−0.07	−0.57 to 0.41	−0.02	0.751
Diabetes self−management behaviours								
three or four behaviours four or more days per week	−0.14	−0.73 to 0.44	−0.03	0.626	0.32	−0.16 to 0.81	0.07	0.190
Diabetes self-efficacy	−0.12	−0.28 to 0.04	−0.10	0.145	−0.06	−0.21 to 0.07	−0.06	0.335

Factors	Univariate analysis				Multivariate analysis			
	Unstandardized coefficients	95% CI	Beta coefficients	P-value	Unstandardized coefficients	95% CI	Beta coefficients	P-Value
Quality of care								
Index of continuity of care	0.52	−0.71 to 1.76	0.05	0.409	0.47	−0.52 to 1.46	0.04	0.351
Continuity of care reported by patients								
A lot of time	0.45	−0.60 to 1.52	0.08	0.457	0.06	−0.78 to 0.91	0.02	0.203
Almost always	0.29	−0.66 to 1.26	0.06		0.52	−0.24 to 1.29	0.11	
Always	−0.13	−1.05 to 0.77	−0.03		−0.04	−0.80 to 0.70	0.004	
Treatment intensification								
Appropriate treatment intensification	−1.50†	−2.05 to −0.94	−0.35	0.000	−0.68†	−1.17 to −0.20	−0.17	0.006
Patient–doctor communication								
Total score = 40	−0.27	−0.87 to 0.32	−0.06	0.370	0.03	−0.47 to 0.54	0.0005	0.902
Patient satisfaction with diabetes care	−0.05†	−0.09 to −0.01	−0.18	0.010	−0.04*	−0.08 to −0.005	−0.13	0.024
Adjusted Model R^2						0.51†		0.000

* P-value <0.05; † P-value <0.01

9.10 The relationship between glycaemic control at baseline and follow-up

Figure 9.5 illustrates the distribution of HbA1c at follow-up: the mean is 8.3% with a standard deviation of 2.0%. The range is 4.1–14.0%. The histogram shows significant positive skew (0.89) and, as a result, Figure 9.6 displays a box-plot of HbA1c at follow-up. The median level is 7.8%, not too dissimilar to the mean, with an inter-quartile range of 6.8–9.6%. The box-plot reveals four 'outliers' with high values of HbA1c, all of them 14.0%.

Although mean HbA1c was higher at follow-up, both means were above target HbA1c levels (HbA1c at baseline 7.9% and HbA1c at follow-up 8.3%) according to the clinical practice guideline from the MISS where the target is HbA1c <7.0% (IMSS 2008).

Figure 9.5: Histogram of HbA1c at follow-up

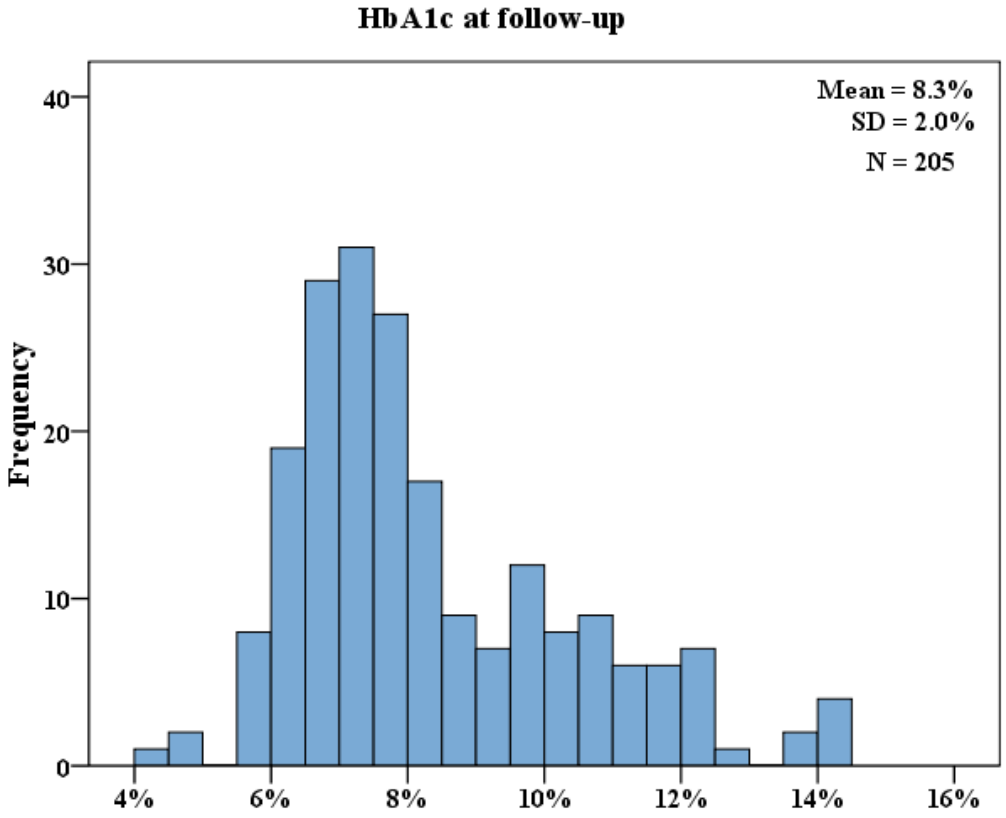


Figure 9.6: Box-plot of HbA1c at follow-up

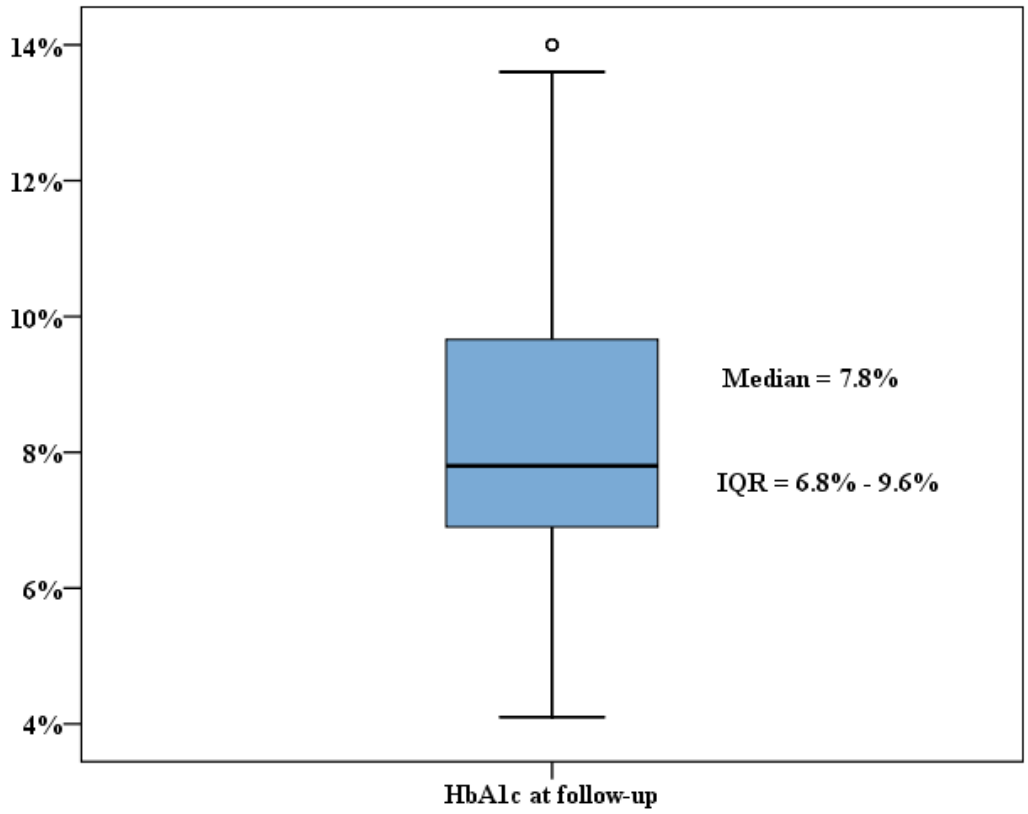


Table 9.27 HbA1c at baseline, follow-up and change

	HbA1c at baseline	HbA1c at follow-up	Change in HbA1c
Mean (SD)	7.9% (2.1)	8.3% (2.0)	0.38 (1.9)
Median (IQR)	7.5% (6.4 to 9.0)	7.8% (6.8 to 9.6)	0.32 (−0.3 to 1.2)

In Table 9.27, HbA1c is dichotomised into good glycaemic control (HbA1c <7.0%) as stipulated in this Thesis based on clinical practice guideline targets and poor glycaemic control (HbA1c ≥7.0%). Over 40% of patients were under good glycaemic control at baseline but this percentage decreased at follow-up. Nearly half of the patients with good glycaemic control at baseline had poor glycaemic control at follow-up (Table 9.28). This table shows that some patients who were initially under control were not at follow-up.

Table 9.28 Glycaemic control at baseline and follow-up

	Glycaemic control at baseline N (%)	Glycaemic control at follow-up N (%)
HbA1c <7.0%	85 (41.5%)	59 (28.8%)
HbA1c ≥7.0%	120 (58.5%)	146 (71.2%)

9.11 Predictors of glycaemic control at follow-up

Triglycerides was not included in this analysis. A number of patients had very high levels of triglycerides, which might unduly affect the regression model. Rather than exclude these patients, further reducing the sample size, it was decided not to include this variable.

In univariate linear regressions, patients had higher HbA1c at follow-up if they had high levels of HbA1c at baseline, were younger, had diabetes for a longer duration, or were prescribed combination therapy. Lower levels of HbA1c at follow-up were related to patients who had had treatment intensification where there was potential to improve HbA1c (Table 9.29). A 1% increase in HbA1c at baseline was significantly associated with 0.55% increase of HbA1c at follow-up (95% CI 0.44 to 0.66, P <0.001). A 10-year increase in age was associated with 0.2% decrease of HbA1c, (95% CI −0.5 to −0.01 P 0.036). Combination therapy was significantly associated with 1.4% increase of HbA1c, compared to patients with monotherapy (95% CI 0.86 to 2.0 P <0.001). HbA1c levels were significantly lower (0.9% reduction of HbA1c) in patients receiving appropriate treatment intensification (95% CI −1.49 to −0.39 P 0.001).

The multivariate linear regression model, that included all variables, explained 36% of the variation in HbA1c at follow-up. Age and appropriate treatment intensification were no longer significant, but HbA1c at baseline and medical prescription remained so. Duration of diabetes and the practice that the patient attended were now significant. A 1% increase in HbA1c at baseline was significantly associated with 0.51% increase of HbA1c at follow-up (95% CI 0.38 to 0.64, P <0.001). Attending practice Nº 9 was significantly associated with 1.2% reduction of HbA1c, compared to patients attending practice Nº 1. The omnibus test P-value for practice was P 0.023. The 10-year increase in diabetes duration was significantly associated with 0.4% increase of HbA1c (95% CI 0.07 to 0.8, P 0.020). Combination therapy was significantly associated with 0.70% increase of HbA1c levels (95% CI 0.13 to 1.27, P 0.015). In the univariate analysis, the association between combination therapy and HbA1c was stronger (1.4% increase of HbA1c, 95% CI 0.86 to 2.0 P <0.001).

When HbA1c at baseline was removed from the model, practice, and medical prescription remained significant. Appropriate treatment intensification was also a

significant predictor. This model explained only 14% of variance in HbA1c. Attending practice Nº 9 remained significantly associated with 1.7% reduction of HbA1c, compared to patients attending practice Nº 1. The omnibus test P-value for practices was P 0.008. Combination therapy remained significantly associated with an increase in HbA1c levels at follow up. The association was stronger than in the analysis controlling for HbA1c at baseline. HbA1c levels were significantly lower (0.61% reduction of HbA1c) in patients receiving appropriate treatment intensification (95% CI −1.18 to −0.03, P 0.038).

HbA1c at baseline was the strongest predictor of HbA1c at follow-up and it was even stronger than treatment intensification (quality of care predictor). There were no self-management variables related to HbA1c at follow-up therefore it was not possible to evaluate the relative importance of self-management and quality of care as predictors of HbA1c. Treatment intensification was the most important quality of care variable.

There were some factors that showed a weak relationship with HbA1c at follow-up. In the univariate analysis, HbA1c was lower in patients attending practice N° 9 compared to patients attending practice N°1. HbA1c was lower in patients without a job compared to patients with a job. HbA1c was higher in patients with longer diabetes duration. In the multivariate analysis including HbA1c at baseline, HbA1c was higher in younger patients. In the multivariate analysis which did not include HbA1c at baseline, HbA1c was higher in patients with longer diabetes duration. HbA1c was lower in patients with a greater number of comorbidities.

Table 9.29 Linear regressions with HbA1c at follow-up as dependent variable

Factors	Univariate analysis			Multivariate analysis					
	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value
HbA1c at baseline	0.55 (0.44 to 0.66)†	0.58	0.000	0.51 (0.38 to 0.64)†	0.53	0.000			
Practice									
Nº 7	0.11 (−0.74 to 0.98)	0.02	0.070	0.17 (−0.58 to 0.94)	0.03	0.023	0.45 (−0.43 to 1.33)	0.08	0.008
Nº 8	0.17 (−0.57 to 0.92)	0.03		0.25 (−0.41 to 0.91)	0.05		0.03 (−0.73 to 0.79)	0.007	
Nº 9	−1.18 (−2.24 to −0.12)	−0.16		−1.18 (−2.14 to −0.22)	−0.16		−1.72 (−2.82 to −0.62)	−0.24	
Nº 10	−0.55 (−1.34 to 0.23)	−0.11		0.49 (−0.23 to 1.22)	0.10		−0.09 (−0.92 to 0.73)	−0.01	
Sampling									
Random sampling	−0.60 (−1.42 to 0.21)	−0.10	0.149	−0.44 (−1.13 to 0.23)	−0.07	0.200	−0.44 (−1.24 to 0.35)	−0.07	0.272

Factors	Univariate analysis			Multivariate analysis					
	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value
Demographic									
Age	−0.02 (−0.05 to −0.001)*	−0.14	0.036	−0.02 (−0.06 to 0.003)	−0.14	0.083	−0.02 (−0.06 to 0.01)	−0.12	0.189
Gender									
Female	−0.04 (−0.62 to 0.53)	−0.01	0.879	0.001 (−0.56 to 0.56)	0.004	0.996	0.04 (−0.60 to 0.70)	0.01	0.882
Marital status									
Without partner	−0.47 (−1.11 to 0.16)	−0.10	0.143	−0.16 (−0.74 to 0.41)	−0.04	0.572	−0.43 (−1.10 to 0.23)	−0.09	0.201
Educational level									
Primary school	−0.43 (−1.12 to 0.24)	−0.10	0.298	−0.32 (−0.94 to 0.28)	−0.07	0.340	−0.53 (−1.24 to 0.17)	−0.12	0.305
Secondary school	−0.01 (−0.85 to 0.82)	−0.002		−0.25 (−1.05 to 0.54)	−0.04		−0.20 (−1.12 to 0.72)	−0.03	
From technician to postgraduate	−0.68 (−1.50 to 0.13)	−0.12		−0.69 (−1.45 to 0.07)	−0.13		−0.71 (−1.59 to 0.17)	−0.13	
Employment status									
Patients without a job	−0.51 (−1.13 to 0.10)	−0.11	0.100	−0.02 (−0.66 to 0.61)	−0.005	0.938	−0.34 (−1.08 to 0.39)	−0.07	0.358

Factors	Univariate analysis			Multivariate analysis					
	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value
Clinical									
Duration of diabetes	0.03 (−0.001 to 0.07)	0.13	0.057	0.04 (0.007 to 0.08)*	0.16	0.020	0.04 (−0.004 to 0.08)*	0.14	0.075
Cholesterol	0.002 (−0.004 to 0.009)	0.05	0.473	−0.001 (−0.008 to 0.005)	−0.03	0.613	0.003 (−0.003 to 0.01)	0.06	0.338
Body mass index									
Overweight	−0.32 (−1.21 to 0.57)	−0.07	0.511	0.40 (−0.35 to 1.17)	0.10	0.415	0.08 (−0.80 to 0.96)	0.02	0.899
Obesity	0.007 (−0.90 to 0.92)	0.001		0.55 (−0.26 to 1.37)	0.13		0.19 (−0.74 to 1.14)	0.04	
Hypertension	0.24 (−0.35 to 0.83)	0.05	0.427	−0.14 (−0.70 to 0.40)	−0.03	0.594	0.22 (−0.40 to 0.86)	0.05	0.477
Comorbidities	−0.05 (−0.24 to 0.12)	−0.04	0.545	−0.12 (−0.29 to 0.05)	−0.09	0.167	−0.16 (−0.36 to 0.03)	−0.12	0.106
Complications	0.12 (−0.34 to 0.58)	0.03	0.604	−0.11 (−0.52 to 0.28)	−0.03	0.563	−0.02 (−0.50 to 0.44)	−0.008	0.905

Factors	Univariate analysis			Multivariate analysis					
	Unstandardized coefficients (95% CI)	**Beta**	**P-value**	**Unstandardized coefficients (95% CI)**	**Beta**	**P-value**	**Unstandardized coefficients (95% CI)**	**Beta**	**P-value**
Beck Depression Inventory									
Mild to moderate depression	−0.008 (−0.64 to 0.62)	−0.001	0.458	−0.04 (−0.61 to 0.53)	−0.009	0.830	−0.02 (−0.69 to 0.64)	−0.005	0.858
Moderate to severe depression	0.68 (−0.21 to 1.58)	0.11		0.33 (−0.50 to 1.18)	0.05		0.35 (−0.62 to 1.33)	0.05	
Severe depression	−0.08 (−1.13 to 0.96)	−0.01		−0.01 (−0.97 to 0.94)	−0.002		−0.08 (−1.20 to 1.02)	−0.01	
Medical prescription									
Combination therapy	1.43 (0.86 to 2.00)†	0.33	0.000	0.70 (0.13 to 1.27)*	0.16	0.015	1.12 (0.48 to 1.77)†	0.26	0.001

Factors	Univariate analysis			Multivariate analysis					
	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value	Unstandardized coefficients (95% CI)	Beta	P-value
Self-management									
Diabetes knowledge	0.02 (−0.04 to 0.10)	0.05	0.450	−0.01 (−0.09 to 0.05)	−0.03	0.625	−0.01 (−0.09 to 0.07)	−0.02	0.746
Self-management behaviours									
3/4 behaviours 4≥ days per week	−0.28 (−0.84 to 0.27)	−0.06	0.321	−0.13 (−0.66 to 0.39)	−0.03	0.624	−0.06 (−0.67 to 0.55)	−0.01	0.842
Diabetes self-efficacy	−0.06 (−0.22 to 0.08)	−0.05	0.393	0.04 (−0.10 to 0.20)	0.04	0.547	−0.03 (−0.21 to 0.14)	−0.03	0.701
Quality of care									
Self-reported continuity of care									
A lot of time	0.18 (−0.83 to 1.20)	0.03	0.805	-0.17 (-1.06 to 0.71)	−0.03	0.737	−0.22 (−1.25 to 0.80)	−0.04	0.909
Almost always	0.40 (−0.51 to 1.32)	0.09		0.11 (−0.66 to 0.89)	0.02		0.08 (−0.81 to 0.99)	0.02	
Always	0.37 (−0.50 to 1.25)	0.09		0.21 (−0.57 to 0.99)	0.05		−0.06 (−0.96 to 0.84)	−0.01	
Treatment intensification									
Appropriate	−0.94 (−1.49 to −0.39)†	−0.23	0.001	0.12 (−0.40 to 0.65)	0.03	0.646	−0.61 (−1.18 to −0.03)*	−0.14	0.038
Patient–doctor communication									
Total score = 40	0.08 (−0.48 to 0.66)	0.02	0.761	0.15 (−0.35 to 0.65)	0.03	0.556	0.05 (−0.53 to 0.63)	0.01	0.865
Adjusted Model R^2				0.36†		0.000	0.14†		0.001

* P-value <0.05; † P-value <0.01

9.12 Model checking

9.12.1 Collinearity

Preliminary steps were taken to avoid collinearity. For example, highly correlated independent variables were not chosen for the final model (e.g. diabetes knowledge and medical prescription knowledge; self-reported continuity of care and the index of continuity of care). The exploratory work in earlier sections of this chapter did not reveal strong inter-relationships between independent variables. However, as a formal test, variance inflation factors were calculated for the multivariable model including baseline HbA1c and they showed that the largest was 4.0. As explained in Chapter 8, VIF >10 generally indicate collinearity. Therefore, there was not strong evidence of collinearity in this model.

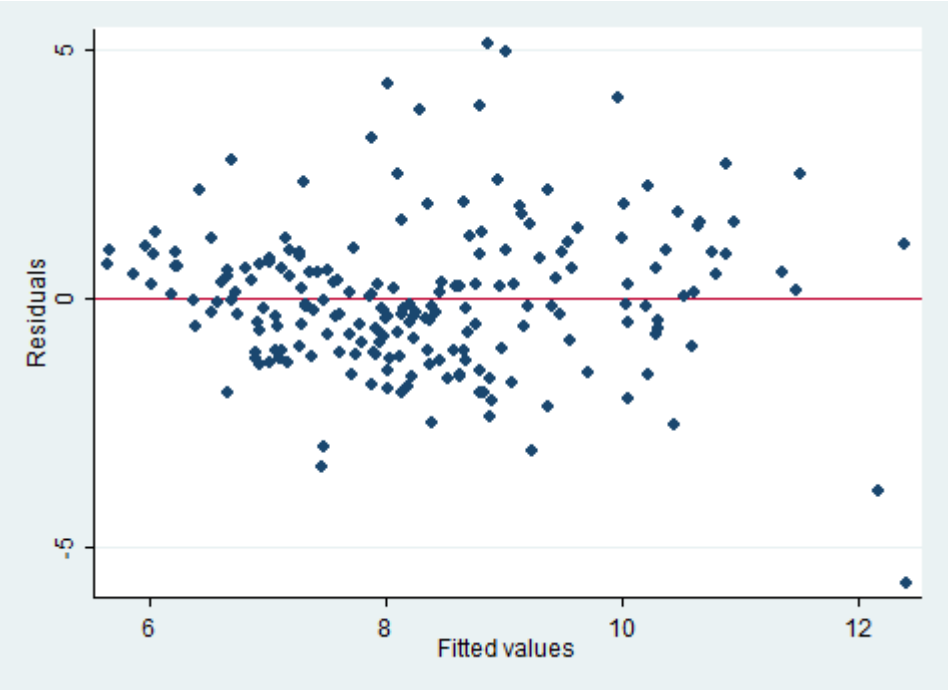
9.12.2 Residuals

Analysis of residuals examines differences between the observed values of the dependent variable and the corresponding values predicted by the regression model (Altman 1991). In a good fitting model, the residuals should be normally distributed, and the most discernible way to test this assumption is with a plot of the residuals against the values of the dependent variable estimated by the regression model, which should reveal a random pattern (zero correlation). Analysis of residuals can also assess outliers (observations markedly deviating from the regression line), linearity (no association between residuals and each independent variable), and homoscedasticity (variability of residuals is constant). The analysis of residuals (Figure 9.7) showed no problematic patterns; variability of the residuals is fairly constant across the range of fitted values (homoscedasticity). Thus, it would appear that the model fits the data well.

9.12.3 Outliers

There are few large residuals, which indicate outlying values (Figure 9.7). The outlying values (residuals < −5 or >5) corresponded to two patients whose residuals were −5.7 and 5.1. Most unusual in these patients was the large change in HbA1c between baseline and follow-up. One patient had HbA1c of 16.5% at baseline and 6.7% at follow-up and the other patient had HbA1c of 7.6% at baseline and 14.0% at follow-up.

Figure 9.7 Analysis of residuals



9.12.4 Leverage

Leverage helps to identify influential observations. The largest leverage was 0.27 in the model. It has been suggested that a leverage greater than 0.2 is considered to be large. Therefore, there were few highly influential observations in the model in Table 9.29 (six patients). These patients had extreme values in some independent variables. For example, a patient was 84 years old, another patient had 32 years' duration of diabetes, and another scored 6 in the Diabetes Knowledge Questionnaire.

9.13 Secondary analysis using interactions

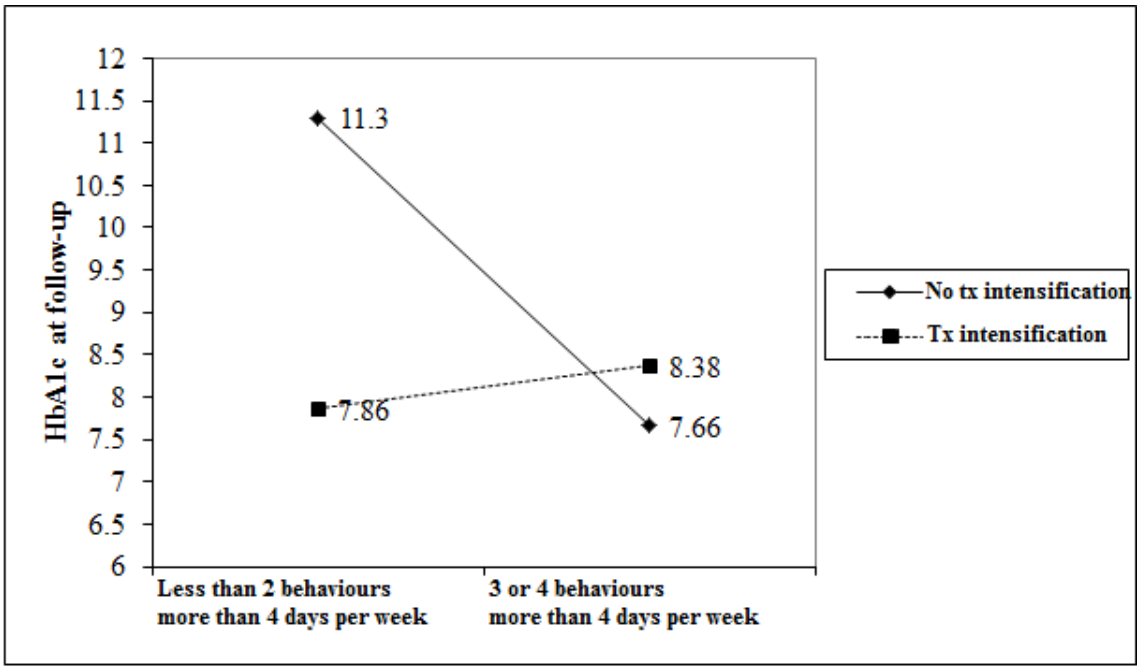
It was not possible to assess the relative importance of self-management and quality of care predicting glycaemic control because there was just one significant predictor (treatment intensification). No self-management variable was significant in the prediction of glycaemic control at follow up.

As a secondary, exploratory analysis, we also explored whether there was an interaction between self-management and quality of care in the prediction of HbA1c levels. This would test whether the effects of self-management on HbA1c were different at different levels of quality of care.

For this analysis, we used the self-management variable based on the SDSCA, and the significant measure of quality of care from the main analysis (treatment intensification).

A significant interaction was found between self-management behaviours and treatment intensification controlling for HbA1c at baseline (Figure 9.8). This interaction shows that if treatment is not intensified, HbA1c is associated with effective self-management. However, if treatment is intensified, self-management behaviour appears to make little difference to HbA1c. The linear regression coefficient of this interaction was 1.04 (95% CI 0.11 to 1.96, P <0.05).

Figure 9.8 Interaction between self-management behaviours (SDSCA) and treatment intensification in their association with HbA1c at follow-up



9.14 Summary

Less than half of potentially eligible patients who attended consultations with general practitioners were approached to take part in the study. Although, the loss of patients at each stage was limited, the overall attrition was such that only 205/468 (44%) patients were eventually included in the main analysis.

This chapter has answered the six research questions of this Thesis. The first research question (included on page 19) was answered through sections 9.3 to 9.6.

The sample in this Thesis was characterised by female patients, those without a job, aged around 60 years, with limited education and relatively poor control of HbA1c. Hypertension and depression are common conditions in patients with diabetes (see section 4.5 Comorbidity in diabetes) and both were frequent in this sample as well. Most of the patients were on combination therapy, which is usual in patients with longer duration of diabetes (Nathan et al. 2009).

Patients were knowledgeable about diabetes but less so in relation to their medical prescriptions. Half of the patients performed more than four self-management behaviours four days or more per week, and patients generally reported high levels of self-efficacy. Patients were seen frequently by their usual general practitioner, and scored high on scales of communication with the general practitioner and satisfaction with diabetes care.

The second research question (included on page 19) was answered in section 9.7.

There were demographic and clinical characteristics related to self-management and quality of care: age, gender, marital status, level of education, practice, FBG, cholesterol, triglycerides, BMI, comorbidities, depression, and medical prescription.

The third research question (included on page 19) was answered in section 9.8.

There were significant relationships within self-management measures. ‘Strong’ knowledge about medical prescription was significantly associated with higher scores in

the Diabetes Knowledge Questionnaire; and performing three or four self-management behaviours on four or more days per week was significantly associated with higher scores in the Diabetes Self-Efficacy scale. However, these relationships were weak.

There were significant relationships within quality of care measures: continuity of care reported by patients (being seen frequently by the usual GP) was associated with higher scores in the continuity of care index, with appropriate treatment intensification, with reporting a total score of 40 in the Patient–Doctor Communication scale, and with having higher scores in the Patient Satisfaction with Diabetes Care scale. Reporting a total score of 40 in the Patient–Doctor Communication scale was associated with higher scores in the Patient Satisfaction with Diabetes Care scale. Higher scores in the Patient Satisfaction with Diabetes Care scale were correlated with higher scores in the index of continuity of care. These relationships were also weak.

There was a significant relationship between self-management and quality of care measures: reporting a total score of 40 in the Patient–Doctor Communication scale was associated with higher scores in the Diabetes Self-Efficacy scale. This relationship was also weak (the odds ratio was close to 1).

The fourth research question (included on page 20) was answered in section 9.9.

There were demographic, clinical, and quality of care factors related to glycaemic control at baseline: occupation, practice, FBG, cholesterol, triglycerides, medical prescription, treatment intensification, communication with general practitioner, and satisfaction with diabetes care.

The final two research questions were answered in section 9.11 (included on page 20).

Univariate linear regressions showed that there were four predictors of HbA1c at follow-up: HbA1c at baseline, age, duration of diabetes, and medical prescription.

Two multivariate models included glycaemic control at follow-up as the dependent variable and explored a number of predictors. The models demonstrated five predictors of glycaemic control: HbA1c at baseline, practice, duration of diabetes, medical prescription, and treatment intensification.

HbA1c at baseline was the strongest predictor of HbA1c at follow-up. There were no self-management variables related to HbA1c at follow-up, therefore it was not possible to evaluate the relative importance of self-management and quality of care as predictors of HbA1c. Treatment intensification was the most important predictor among quality of care variables.

Chapter 10
Discussion

10.1 Introduction

The aim of this study was to evaluate the individual contribution and relative importance of self-management and quality of care in glycaemic control in patients with type 2 diabetes. A review (Chapter 6) highlighted that few published observational studies have measured the individual contribution and none has measured the relative importance of these factors on glycaemic control in patients with type 2 diabetes. Moreover, these previous studies have focused on specific aspects of self-management, such as medication adherence (O'Connor et al. 2004; Schmittdiel et al. 2008) and diet and exercise (Parchman et al. 2002); or specific aspects of quality of care, such as continuity of care (Parchman et al. 2002).

There was just one significant predictor of glycaemic control at six-month follow-up in this Thesis (treatment intensification), supporting previous literature on the importance of this variable (Sidorenkov et al. 2011). There were no significant predictors among the self-management variables measured, and thus the relative importance of self-management and quality of care could not be explicitly compared. The findings of this Thesis would suggest that quality of care (treatment intensification) was more important than self-management as a predictor of glycaemic control, at least in the context of Mexican primary care.

Secondary analyses did suggest an interaction between self-management behaviours and treatment intensification. This suggested that in patients who did not receive treatment intensification when indicated, greater numbers of self-management behaviours predicted significantly lower HbA1c at six months. This interaction has not been reported previously.

The chapter starts with a discussion about the methodological strengths and limitations of the Thesis, followed by a synthesis of the existing empirical literature on self-management and quality of care in diabetes and how it compares to the results of this Thesis. The implications of the Thesis for policy, practice, and research are then discussed before finishing with overall concluding comments.

10.2 Methodology

The approach taken in the longitudinal cohort study has significant strengths. The study measured various aspects of *both* self-management and quality of care, a comprehensive approach which has not been reported in the literature up to now. The analysis allowed statistical control for relevant covariates (demographic and clinical), and the follow-up rate of 90% was higher than the recommended acceptable rate of 80% (Altman 2000; Kristman et al. 2004) meaning that the risk of bias in the analysis due to attrition was small. Particular strengths and limitations are discussed in the following paragraphs.

10.2.1 Sampling bias

Sampling bias is a 'systematic error due to the methods or procedures used to sample or select the study subjects, specimens, or items (e.g. scientific papers), including errors due to the study of a non-random sample of a population' (Porta 2008, p. 222).

Sampling bias might have occurred in this study because most of the participants were selected using consecutive sampling (a non-random method) of diabetic patients from the 5 MISS practices in the city of Aguascalientes. It was necessary to sample consecutively due to the time and financial constraints of the study; however, a random sample was also drawn in order to evaluate whether the consecutive sample was representative (i.e. whether it suffered from selection bias). Fewer than 30 patients selected as part of the random sample responded and, coupled with the lack of population data from MISS, this makes quantifying response biases more difficult. Characteristics of the consecutive and random sample participants (at the analytical stage) are compared in Table 10.1 and shows that there were differences between the samples in terms of gender, BMI, hypertension and depression. The consecutive sample included fewer women (61.5% vs. 71.9%), fewer obese patients (39.0% vs. 53.1%), fewer patients with hypertension (65.6% vs. 75.0%), and more patients with moderate to severe depression according to the Beck Depression Inventory (14.9% vs. 3.1%).

Table 10.1 Consecutive vs. random samples at baseline

Variables	Consecutive sample (n=195)	Random sample (n=32)
Practice n (%)		
N° 1	56 (28.7)	9 (28.1)
N° 7	29 (14.9)	5 (15.6)
N° 8	49 (25.1)	10 (31.2)
N° 9	19 (9.7)	2 (6.2)
N° 10	42 (21.5)	6 (18.8)
Demographic		
Age, mean (SD)	61.0 (10.2)	59.6 (10.1)
Gender, n (%)		
Male	75 (38.5)	9 (28.1)
Female	120 (61.5)	23 (71.9)
Marital status		
With partner	146 (74.9)	22 (68.8)
Without partner	49 (25.1)	10 (31.2)
Educational level, n (%)		
Illiterate	18 (9.2)	3 (9.4)
Semiliterate	50 (25.6)	7 (21.9)
Primary school	62 (31.8)	13 (40.6)
Secondary school	30 (15.4)	3 (9.4)
From technician to postgraduate	35 (17.9)	6 (18.8)
Employment status, n (%)		
Patients with a job	53 (27.2)	7 (21.9)
Patients without a job	142 (72.8)	25 (78.1)
Clinical		
Duration of diabetes, median (IQR)	8.0 (4.0 – 15.0)	8.7 (3.0 – 13.8)
HbA1c at baseline, mean (SD)	7.9 (2.1)	8.1 (2.1)
FBG, mean (SD)	162.6 (68.6)	168.0 (66.6)
Cholesterol, mean (SD)	206.7 (38.9)	196.1 (42.3)
Triglycerides, median (IQR)	194.0 (142.0 – 258.0)	190.0 (150.0 – 222.7)
Body mass index, n (%)		
Normal weight	25 (12.8)	4 (12.5)
Overweight	94 (48.2)	11 (34.4)
Obesity	76 (39.0)	17 (53.1)
Hypertension, n (%)		
No	67 (34.4)	8 (25.0)
Yes	128 (65.6)	24 (75.0)
Comorbidities, median (IQR)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.0)
Diabetes complications, median (IQR)	0 (0)	0 (0 – 0.7)
Beck Depression Inventory, n (%)		
None to minimal depression	91 (46.7)	14 (43.8)
Mild to moderate depression	61 (31.3)	14 (43.8)
Moderate to severe depression	29 (14.9)	1 (3.1)
Severe depression	14 (7.2)	3 (9.4)
Medical prescription, n (%)		
Monotherapy	61 (31.3)	12 (37.5)
Combination therapy	134 (68.7)	20 (62.5)

Variables	Consecutive sample (n=195)	Random sample (n=32)
Self-management		
Diabetes knowledge, mean (SD)	15.6 (3.6)	16.1 (3.5)
Medical prescription knowledge, n (%)		
Weak knowledge	135 (69.2)	20 (62.5)
Strong knowledge	60 (30.8)	12 (37.5)
Diabetes self-management behaviours, n (%)		
0-2 behaviours 4 or more days per week	87 (44.6)	16 (50.0)
3 or 4 behaviours 4 or more days per week	108 (55.4)	16 (50.0)
Diabetes self-efficacy, mean (SD)	7.1 (1.7)	6.6 (1.6)
Quality of care		
Index of continuity of care, mean (SD)	0.7 (0.2)	0.6 (0.2)
Continuity of care reported by patients		
Some of the time or less frequent	29 (14.8)	3 (9.3)
A lot of time	31 (15.9)	9 (28.1)
Almost always	57 (29.2)	8 (25.0)
Always	78 (40.0)	12 (37.5)
Treatment intensification, n (%)		
Inappropriate treatment intensification	81 (41.5)	13 (40.6)
Appropriate treatment intensification	114 (58.5)	19 (59.4)
Patient-doctor communication scale, median (IQR)	37.0 (25.0 – 40.0)	35.0 (29.2 – 40.0)
Patient satisfaction with diabetes care, median (IQR)	38.0 (31.0 – 42.0)	36.0 (32.2 – 42.2)

SD=standard deviation;IQR=interquartile range.

The consecutive sample consisted of 10% fewer women compared to the random sample. Women have been reported to integrate management into their daily lives more often than men (Mathew et al. 2012). Self-management has been reported more frequently by women than men (Salcedo-Rocha et al. 2008).The consecutive sample also included more patients with depression and depression has been associated with decreased self-management and quality of care in previous studies (Ciechanowski et al. 2000; Egede et al. 2009; Egede and Osborn 2010; Gonzalez et al. 2007; Gonzalez et al. 2008). Thus, gender breakdown and the frequency of more severe depression might have affected the reporting of the two core variables (self-management and quality of care) in the consecutive sample; resulting in lower reported levels of these variables compared to the random sample.

The intended sample size was 405 patients, representing 1.5% of the registered practice population with diabetes. At the end of the study, the total analysis sample was 205 patients (patients who completed follow-up). Eighty seven percent of the analysis sample was patients selected as part of the consecutive sample. This consecutive sample might have included particular patient-types (e.g. more likely to attend their scheduled appointment, sicker or with better glycaemic control). Sometimes there was more than one patient attending their appointment at the same time and the researcher approached the first patient who attended their appointment. Approaching the first patient might have introduced interviewer bias because interviewers might have been 'drawn' to a particular patient-type (e.g. same gender to the interviewer). Attrition might also have introduced bias: patients with a more severe condition, difficulties in terms of meeting the time and cost of attending their laboratory evaluation[3], dissatisfaction with their GP, and/ or a lack of interest could have been more likely to withdraw from the study. Patients recruited at home for the random sample could have been less mobile or less active (including economically active) compared to patients who were recruited within the practice.

Despite these differences, the final sample in the analysis had similar demographic characteristics to the general population of MISS patients. Vazquez-Martinez et al. (2006) reported that amongst patients with diabetes who were registered at MISS 56% were female, 87% were ≥40 years old, 96% had some level of education, 43% were

[3] Laboratory evaluations do not have an extra cost for the patient but they need to spend money to travel to the practice.

overweight and 35% were obese (Vazquez-Martinez et al. 2006). These characteristics are similar to the sample in this Thesis: 62.4% were female, 91.2% had some level of education, 47.8% were overweight and 40.0% were obese.

The intended sample size of 405 would have represented 1.5% of the total population of patients with diabetes at MISS in Aguascalientes. At follow-up, only 51% of this number had consented to participate and provided complete data; these were mainly patients routinely attending their practice (consecutive sample). The average time between baseline and follow-up data collection was 5.8 months. It is likely that a more noticeable change will be observed with a longer follow-up period. Further research, conducted on a large(r), randomly selected sample of patients with diabetes and followed up over a longer time period, would make for more generalisable results. However, more than half of patients from the random sample could not be contacted in their homes for various reasons (they were not living at that address anymore; the address was not found; or there was no-one at home at the time of the visit). Therefore, future research needs to take account of this in any sample size calculations and maximise efforts to contact these patients.

10.2.2 Recruitment and sample size

Poor recruitment can impact on the external validity of research studies (Grimes and Schulz 2002). Most of the potential participants for the research presented in this Thesis were approached and recruited while attending consultations in practices. There were five practices in the city of Aguascalientes and patients were sampled from all the practices. Although the sample was taken from a single geographical location, patients who attend MISS practices in Mexico are relatively homogenous in terms of socioeconomic level (the majority are employed workers and their families).

Practices had at least 10 GPs per session and it was usual that there was more than one potential participant attending a consultation simultaneously making it practically impossible to approach all potential participants. It was estimated that around half of the potential participants were not approached. The fact that potential participants attended more quickly than they could be approached reflects the reality of busy surgeries but is likely to introduce less bias than people refusing to participate, because those who could not be approached due to logistical issues might be expected to show less systematic

bias in their characteristics than those patients who actually refuse to take part when approached.

Half of the patients approached were not included in the analysis because they did not agree to participate, or did not attend a blood test, or were lost at six-month follow-up. Unwillingness to participate and loss at follow-up are examples of *selection bias* (Alonso et al. 2006; Kristman et al. 2004). Selection bias can affect study results because associations might differ between participants and non-participants (Hernan et al. 2004). The effects of selection bias can be minimised by achieving the maximum participation and follow-up rate possible (Kristman et al. 2004). Selection bias via attrition should have been minimised in this Thesis because the follow-up rate was high (90%).

We were unable to collect data on non-participants, and comparisons were only performed in (a) patients at baseline with and without complete data (b) patients with and without follow-up data, rather than participants and non-participants. Patients at baseline with complete data had significantly lower median triglycerides than patients without complete data (194mg/dl vs 241 mg/dl, 2.2 mmol/l vs. 2.7 mmol/l). Patients retained at follow-up were more likely to perform self-management behaviours (57% vs. 32%), and reported higher patient–doctor communication (median 37 vs. 28.5) and satisfaction with diabetes care (median 38 vs. 33.5) than those dropping out. Therefore, the study results are based on those with higher levels of the two core independent variables in the study. Internal validity may be affected because of reduction of variability in these independent variables. This limitation also affects external validity because the results may not generalise to the wider patient population. However, loss to follow-up was only 10%. It has been suggested that 20% loss at follow-up does not compromise the reliability of the findings in RCTs (Altman 2000; Kristman et al. 2004).

Additional strategies could be employed in future research to overcome these limitations. For example, Watson and Torgerson (2006) suggested the use of lay advocates (i.e. enrolled and trained participants recruiting more potential participants), alternative strategies for contacting patients (i.e. telephone reminders after the initial invitation), and monetary incentives for patients. Based on the experience in this study, I would recommend involving more recruitment staff to approach potential participants, and recruiting more patients from home visits who are registered with a GP but who do

not visit him or her frequently. A home visit would allow more time to explain the research project to potential participants and clarify any questions about participation.

The required sample size was not achieved (n=405) and the study may not have been powerful enough to detect the size of the effect that it set out to detect. The precision of estimates from the regression are necessarily limited.

10.2.3 Measurement

A review of RCTs suggested that unpublished scales can be a source of bias (Marshall et al. 2000), as studies reporting successful interventions are more likely to use unpublished scales. These problems are best avoided using valid and reliable measurements (Salter et al. 2007). Although these reviews are focused on RCTs, any kind of research should use valid and reliable measurements to produce 'meaningful and replicable data' (Salter et al. 2007, p. 1010).

10.2.3.1 Validation of the Patient-Satisfaction with Diabetes Care (PSDC) and Patient-Doctor Communication Scales (PDCS)

The scales for patient–doctor communication and satisfaction with diabetes care used in this Thesis have not been published in a peer-reviewed journal. These scales were used because there were no available measurements which were published in Spanish and both scales were specific for patients with type 2 diabetes. Even though data were unpublished, both scales were developed and tested.

The scale of satisfaction with diabetes care was validated (in terms of content validity) with a focus group of researchers who identified dimensions and items of satisfaction with diabetes care (in general practice) and a focus group of people with type 2 diabetes who confirmed that items were comprehensible and unambiguous (Prado-Aguilar 2007). The final items were selected using factor analysis. These items explained 68% of the variance of the scale. Cronbach's alpha coefficient was 0.74 showing that the scale of satisfaction with diabetes care was reliable.

The patient–doctor communication scale was developed and tested within the MISS context. The PDCS was developed through a literature search (Velazquez-Abad 2010).

A focus group of patients with type 2 diabetes confirmed that items were comprehensible and unambiguous. These patients were a sample of Mexicans with type 2 diabetes under the primary care of MISS. Eight of 19 items explained 84% of the variance of the scale in a factor analysis. The reliability of the Patient–Doctor Communication scale was 0.90 (Cronbach's alpha).

Velazquez-Abad (2010) performed a literature review to find a suitable instrument for testing criterion validity of the PDCS, the European Task Force on Patient Evaluations on General Practice Care (EUROPEP) instrument (Grol et al. 2000). The EUROPEP was selected because it includes similar items to the Patient–Doctor Communication scale and the EUROPEP has been used in the context of primary care. Velazquez-Abad (2010) translated and adapted the EUROPEP using the translation process suggested by Streiner and Norman (Streiner and Norman 1995). The first step was to translate the EUROPEP from English to Spanish by 2 bilingual health professionals who were knowledgeable about patient-doctor communication. The second step was to back-translate from Spanish to English by another bilingual health professional who was not involved in the first translation. The third step was to pilot testing of the pre-final version of the instrument by patients with type 2 diabetes. The final step was to produce a final version with comprehensible and unambiguous items.

The PDCS version with 8 items was correlated with the Spanish translation of the EUROPEP. This correlation was used to test criterion validity resulting in Spearman correlation of 0.71.

Velazquez-Abad (2010) followed the standard procedures to develop and validate the PDCS as well as the standard procedures to translate and adapt the EUROPEP using it for the validity testing of the PDCS. However, cultural aspects involved in the EUROPEP were not addressed. For example, GPs are not expected to speak to patients on the phone at MISS practices. The EUROPEP has an item asking patients' opinion about being able to speak to the GP on the phone. This kind of questions might produce biased results in the MISS context where most patients would choose the negative extreme answer for the question about speaking to the GP on the phone. Velazquez-Abad (2010) reported a mean of 1.51 for the question 'What is your opinion of the general practitioner and/or general practice over the last 12 months with respect to being

able to speak to the general practitioner on the telephone?' which has a response scale from 1 to 5 (from 'poor' to 'excellent').

Although all self-report scales were valid and reliable, it may be possible that interviews affected patients' responses through 'reporting' bias (Delgado-Rodriguez and Llorca 2004). Reporting bias means that 'participants can 'collaborate' with researchers and give answers in the direction they perceive are of interest (obsequiousness bias)' (Delgado-Rodriguez and Llorca 2004, p. 639). For example, self-management behaviours were reported using a response scale of days per week and reporting bias would occur if patients reported performing self-management behaviours more frequently than patients from other studies. A previous study reported similar levels of self-management behaviours to this Thesis using the same questionnaire and including Latino patients with type 2 diabetes (Rosland et al. 2008). The same frequency was reported for taking diabetes medications seven days per week (84%). Foot care was even higher in the study of Rosland et al. (2008) (77%) compared to this Thesis (55%). However, this does not avoid the potential that both studies suffered from this bias.

10.2.3.2 Culture and self-efficacy

Self-efficacy was measured using the Diabetes Self-Efficacy Scale, developed by the Stanford Patient Education Research Centre for use as one of the outcomes of the Diabetes Self-Management Programme (Lorig 1996). Kendall and Rogers (2007) concluded that although the Diabetes Self-Management Programmes promotes a 'social model', the focus on self-efficacy and the patient reflects an 'individualistic', American culture (Klassen 2004).

It is possible that the Diabetes Self-Efficacy Scale might not make the same sense to respondents from other cultures, such as Mexicans who have been described as having a 'collectivist' culture (Klassen 2004) with strong 'collective identity' and 'group solidarity' (Klassen 2004, p. 208). 'Collectivist' cultures attribute more importance to the group than to the individual.

Bandura suggests that the determinants of self-efficacy can vary between different cultures:

> '… cultural values and practices affect how efficacy beliefs are developed, the purposes to which they are put and the way in which they are best exercised in particular cultural milieus' (Bandura 1997b p. 32).

> 'Culture may affect …. which information is selected and how it is weighted and integrated in people's self-efficacy judgements' (Bandura 1997a, p. 151).

Burke et al. (2009) suggest that confidence, which is a crucial element of self-efficacy, can be 'established through relationships and connections with others rather than an individually acquired and assessed attribute' (Burke et al. 2009, p. 126). Self-efficacy might be defined and perceived differently among individualist and collectivist cultures.

Cultural perceptions of self-efficacy might raise problems using measures across cultures. For example, in this Thesis, when participants answered the self-efficacy scale, some of them referred to behaviours instead of confidence. It seems that the concept of 'confidence' was not clear for them. The interviewer had to remind participants that they were asked about their confidence to do the activities included in the scale.

There are no published papers about the use of the Diabetes Self-Efficacy scale in Mexico but other self-efficacy scales have been used. Del Castillo Arreola et al. (2012) developed and validated the Diabetes Treatment Self-Efficacy scale in a sample of Mexican patients with Type 2 diabetes (Del Castillo Arreola et al. 2012). The Diabetes Treatment Self-Efficacy scale was developed based on the self-efficacy theory proposed by Bandura in 1997. Both The Diabetes Treatment Self-Efficacy scale and the Diabetes Self-Efficacy scale include items about confidence to perform eating and exercise behaviours, among others. Del Castillo Arreola et al. (2012) found that the Diabetes Treatment Self-Efficacy scale showed good convergent validity with psychological well-being ($r=0.32$, $P<0.01$) and good divergent validity with distress ($r=-0.42$, $P<0.01$). The Diabetes Treatment Self-Efficacy scale also showed good internal consistency (Chronbach α 0.83). Self-efficacy has been also studied in Mexico in terms of weight control in adolescents (Guzman-Saldana et al. 2011), weight control in children (Shamah Levy et al. 2012), and in adolescent drug addicts (Lopez-Torrecillas et al. 2005). The findings from these studies show that self-efficacy has been measured within the Mexican context and the self-efficacy scales have shown good validity and internal

consistency despite the collectivist Mexican culture, which suggests that the use of the measures in the current Thesis is valid.

10.2.3.3 Treatment intensification

Treatment intensification was measured as a predictor of quality of care in this Thesis and extracted from medical records. The measurement of treatment intensification is limited because it deals only with increases in dosage or the addition of more medications. This measure does not take into account the trade-offs between risks and benefits of intensifying medications. The aim of treatment intensification in diabetes is to achieve recommended HbA1c levels according to patient context, with a target level of <7% in Mexico (IMSS 2008). The ADA (2012) suggests the same target except in the presence of a history of severe hypoglycemia, limited life expectancy, advanced diabetes complications, and multiple comorbidities, where it is recommended to achieve 'less-stringent' HbA1c <8% (ADA 2013). A 'less-stringent' HbA1c is also recommended for patients with cardiovascular disease or cardiovascular risk factors (Gerstein et al. 2008). Previous studies of treatment intensification have discussed the limitation of identifying patients who are not appropriate candidates to receive treatment intensification (Schmittdiel et al. 2008) or patients who might refuse to receive additional medications (Katon et al. 2009). but other studies have not addressed it (Fu et al. 2011; Grant et al. 2011).

The following paragraphs provide information about the number of patients who were 'inappropriate candidates' for treatment intensification in this Thesis. These included patients with recorded hypoglycaemic episodes, limited life expectancy, diabetes complications, and multiple comorbidities.

There was information in this Thesis from medical records about blood glucose measurements and blood glucose levels (previous 12 months from recruitment). There is no system of repeat prescriptions in MISS. Instead, patients with type 2 diabetes are seen by GPs on a monthly basis as part of the care provided by MISS to patients with long-term conditions. It is expected that GPs examine blood glucose levels and register them in the medical records. Therefore, there was a potential blood glucose measurement for every month (12 months in total). Average measurement of blood glucose was five measurements during the period of the previous 12 months from

recruitment. Mean fasting blood glucose levels per month was from 134.2 mg/dl (SD 47.9, 7.4 mmol/l, SD 2.6) to 154.3 mg/dl (SD 55.58.5 mmol/l, SD 3.0) There were nine patients with blood glucose levels <70 mg/dl (<3.8 mmol/l) during this period (three of them with two hypoglycaemic episodes). These blood glucose levels ranged from 42 to 69 mg/dl (2.3–3.8 mmol/l). Hypoglycaemia was defined as blood glucose levels <70 mg/dl (<3.8 mmol/l) in Chapter 4. Therefore, there were nine patients with hypoglycaemic episodes in this Thesis representing 4% of the final sample (n=205).

Limited life expectancy refers to patients with 'very long duration of diabetes' and 'advanced age/frailty' (ADA 2013, p. S21). There is no consensus cut-off point for duration of diabetes and advanced age for limited life expectancy but results from previous trials of tight glycaemic control suggest that patients with more than 12 years of diabetes can have adverse effects from intensive glycaemic control (Skyler et al. 2009) as can patients >60 years old (Lehman and Krumholz 2009). There were 66 patients with 12 or more years of diabetes duration in this Thesis representing 32% of the sample (n=205). These 66 patients were potentially inappropriate candidates for treatment intensification.

Diabetes complications and comorbidities were measured in this Thesis. Seventy-six per cent of patients did not report any diabetes complications but it might be possible that they had complications recorded in their medical records. However, most patients reported at least one comorbid condition (85%).

It might be necessary to use additional methods to confirm that patients are suitable candidates for treatment intensification. I would recommend including a more thorough evaluation of potential participants in future research of treatment intensification to confirm whether treatment intensification is appropriate, and duration of diabetes (<12 years) could be a starting point. Additionally, patients with type 2 diabetes and hypoglycaemic episodes may also not be appropriate. Hypoglycaemic episodes have been reported in 3.5–16.2% of patients with type 2 diabetes (Gerstein et al. 2008; Sarkar et al. 2010). Patients under intensive treatment have higher rates of hypoglycaemic episodes (16.2%) than patients under standard treatment (5.1%) (Gerstein et al. 2008). Three antidiabetic oral medications were more frequent in patients under intensive treatment than patients under standard treatment (59.1% vs. 32.8%, respectively) (Gerstein et al. 2008). Other factors have been related to risk of hypoglycaemia, such as

previous hypoglycaemic episodes, insulin therapy, and macrovascular (i.e. heart failure) and microvascular complications (i.e. acute renal failure) (Quilliam et al. 2011). These factors might help researchers to identify which patients are suitable candidates in studies about treatment intensification.

10.2.3.3.1 HbA1c thresholds

Appropriate HbA1c thresholds have not been agreed internationally and there has been recent debate about this. Table 10.2 shows that different HbA1c thresholds have been suggested based on patient characteristics. These thresholds are recommended jointly by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) and are based on large randomised controlled trials including the UK Prospective Diabetes Study (UKPDS), the Veterans Affairs Diabetes Trial (VADT), the Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE), and the Action to Control Cardiovascular Risk in Diabetes (ACCORD) (Inzucchi et al. 2012). The UKPDS focused on younger, healthier patients without long-standing type 2 diabetes and found evidence of benefits from adopting a stringent HbA1c threshold (<7.0%) (Holman et al. 2008). The UKPDS showed that patients with lower HbA1c levels had lower risk of microvascular disease, myocardial infarction and death (Holman et al. 2008). In the case of older patients with long-standing type 2 diabetes, the VADT, ADVANCE and ACCORD trials also showed benefits from a stringent HbA1c threshold (6.0% to 6.5%) in terms of lower risk of microvascular complications (ADA 2013). However, these trials also found serious negative consequences: more patients with severe hypoglycaemia in the intensive glycaemic control arms (aiming a more stringent HbA1c threshold) than in the standard glycaemic control arms in both VADT and ACCORD studies (21.2% vs. 9.9% for VADT and 16.2% vs. 5.1% for ACCORD) and an increase in mortality in the ACCORD trial (Skyler et al. 2009). The less stringent HbA1c threshold (<8.0%) was derived from the VADT and ACCORD trials to reduce serious negative consequences.

Table 10.2 Recommendations for HbA1c thresholds from ADA and EASD related to patient characteristics (Inzucchi et al. 2012)

Level of glycaemic control	HbA1c thresholds	Patient characteristics
Standard	<7.0%	• Most patients
More stringent	<6.5%	• short disease duration • long life expectancy • no significant cardiovascular conditions • without adverse effects of treatment like hypoglycaemia
Less stringent	7.5 - 8.0%	• long-standing diabetes • limited life expectancy • advanced complications • extensive comorbid conditions • history of severe hypoglycaemia

10.2.3.3.2 Treatment intensification and quality of life

The analyses for this Thesis were undertaken on the assumption that treatment intensification in the context of raised HbA1c was generally an appropriate measure of the quality of care. However, it is possible that treatment intensification could be associated with reductions in quality of life among patients if it leads to additional burden or anxiety. The data collection procedure for this Thesis did not include assessment of quality of life at 6 months and was therefore unable to assess any impact. Below, the literature on the relationship between treatment intensification and quality of life is reviewed.

Searches were performed in MEDLINE and Google Scholar using the terms ‘diabetes’, ‘quality of life’, and ‘treatment intensification’ providing 542 titles. There were 12

relevant studies reporting associations between treatment intensification and quality of life. Table 10.3 shows that the relationship between quality of life and treatment intensification is very variable. Most of the studies were cross-sectional (n=8) and sample sizes varied from 20 to 5535 patients. Five studies reported that treatment intensification was associated with lower quality of life (Glasgow et al. 1997;Jacobson et al. 1994;Keinanen-Kiukaanniemi et al. 1996;Mayou et al. 1990;Petterson et al. 1998;van der Does et al. 1998). Two studies reported that treatment intensification was associated with improved quality of life (Goddijn et al. 1999;Menard et al. 2007), but both of these studies were fairly small in size (<100 patients). Four studies did not find any association between treatment intensification and quality of life (Eiser et al. 1992;Gilden et al. 1990;Peyrot and Rubin 1997;UKPDS 1999). The evidence about the association between treatment intensification and quality of life is not conclusive and the studies showing this evidence varied in terms of design, sample size and quality of life measure.

Quality of life was not measured in this Thesis, and the data in Table 10.3 shows no consistent relationship between treatment intensification and quality of life. The sample in this Thesis was already under medical treatment and received treatment intensification of oral diabetic medications without the addition of insulin. The evidence varies by study with examples of both positive and negative effects of intensive treatment (e.g. insulin vs. oral diabetic medications) on quality of life (Mayou et al 1990; Jacobson et al 1994; Keinanen-Kiukaanniemi et al 1996; Glasgow et al 1997; Peterson et al 1998; Van der Does et al 1998). Therefore, it is not possible to predict what effects treatment intensification might have on quality of life in the sample of patients included in this Thesis.

Table 10.3 Quality of life and diabetes treatment regimen

Author	Study design	Sample size	Quality of life instrument	Results
Mayou et al (1990)	Cross-sectional	Adult patients with type 1 diabetes (57) and type 2 diabetes (121)	The Profile of Moods States (POMS) and the Social Difficulty Questionnaire	Insulin treatment was significantly associated to worse quality of life
Gilden et al (1990)	Cross-sectional	20 patients with diabetes, aged 60 to 79 years	Bradley's Well-Being and Treatment Satisfaction questionnaires	No significant differences between patients treated with insulin and those who were not
Eiser et al (1992)	Cross-sectional	69 patients with type 1 diabetes, aged 15 to 25 years	The Diabetes Quality of Life Measure (DQOL)	There was no relation between quality of life and insulin regimens
Peyrot and Rubin (1997)	Intervention 1-week outpatient diabetes education program	578 adult patients with diabetes	The Centre for Epidemiological Studies Depression and the Zung Self-Rating Anxiety questionnaires	There were no significant differences in quality of life between patients with or without insulin treatment

Author	Study design	Sample size	Quality of life instrument	Results
UKPDS (1999)	Cross-sectional and longitudinal studies	Adult patients with type 2 diabetes Cross-sectional sample – 5535 patients Longitudinal sample – 184 patients	Work Satisfaction, POMS, Cognitive Failures Questionnaire, Symptoms, and the EUROQOL Quality of Life Scale (EQ-5D)	Therapeutic policies (conventional vs. intensive treatment) did not have any effect on quality of life
Jacobson et al (1994)	Cross-sectional	Adult patients with type 1 diabetes (111) and type 2 diabetes (129)	The DQOL and the Medical Outcome Study Health Survey 36-Item Short Form (SF-36)	Type of treatment (diet and exercise vs. oral medications; oral medications vs. insulin) was associated with worsening quality of life
Keinanen-Kiukaanniemi et al (1996)	Cross-sectional	1804 adult patients with diabetes	The Nottingham Health Profile	Type of treatment (diet and exercise vs. oral medications; oral medications vs. insulin) was associated with worsening quality of life

Author	Study design	Sample size	Quality of life instrument	Results
Glasgow et al (1997)	Cross-sectional	2056 adult patients with diabetes	The Short Form (SF-20) of the General Health Survey	Insulin treatment was related to lower quality of life in patients with type 2 diabetes
Peterson et al (1998)	Cross-sectional	734 older patients with diabetes	The Well-Being Questionnaire and the Diabetes Treatment Satisfaction Questionnaire	Quality of life was lower in insulin-treated patients
Van der Does et al (1998)	Randomised trial with 1-year follow-up	174 adult patients with diabetes	The type 2 Diabetes Symptom Checklist (DSC-type 2), the Dutch shortened version of the POMS, and the Affect Balance Scale (ABS)	Treatment intensification was associated with lower quality of life

Author	Study design	Sample size	Quality of life instrument	Results
Goddijn et al (1999)	Longitudinal	94 adult patients with type 2 diabetes	The Diabetes Health Profile (DHP) and the RAND 36-item Health Survey I.0 (RAND-36)	Quality of life was improved in patients with type 2 diabetes whom received treatment intensification (insulin) but these patients also reported more problems with social functioning and pain
Menard et al (2007)	12-month randomised trial	72 adult patients with type 2 diabetes	The DQOL	Quality of life was improved in patients under intensive multi-therapy (individual and group education on lifestyle and pharmacological therapy)

10.2.4 Design and analysis

Initial recruitment was slow, indicating that it would not be possible to recruit 405 patients in the allotted time: the projected sample size at six months being in the region of 250–300. This sample size was still sufficient to provide 70% power to detect the required difference in correlations, assuming a correlation of 0.3 between self-management and quality of care (initial power calculation was 75%). However, the correlations between self-management and quality of care in this study never reached that level, and the study lacked power to detect smaller correlations.

The main analysis included a final model with 33 coefficients and a final sample size of 205 patients. Rules of thumb have been suggested to estimate an optimal ratio between participants and predictors. Tabachnick and Fidell (2001) discussed some of these rules of thumb:

1) allowing 5 participants per predictor (Green 1991)
2) 15 to 25 participants per predictor (Schmidt 1971)
3) 400 participants per 9 or 10 predictors (Nunnally 1978).

One rule of thumb recommended for a multiple correlation was $n \geq (50 + 8m)$ (where n is the sample size and m is the number of predictors). For this Thesis, the required sample size based on this formula would be 314, compared to the achieved sample size of 205 participants. Although the sample size in this Thesis might have not been sufficient, it was important to include all potential predictors because of possible relationships among them (Altman 1991). However, including all potential predictors might also be a source of confounding between self-management, quality of care, and glycaemic control. Strategies to control confounders have been suggested and some are included in the next section.

10.2.5 Strategies to control confounders

My aim was to determine if self-management and quality of care have a causal effect on glycaemic control. The validity of any study which explores the association between independent and dependent variables to make such inferences is threatened by known or unknown confounders. Confounders are factors related to both independent and

dependent variables. Although these factors are part of 'real life relationships' (Ajetunmobi 2002), there are experimental designs and/or statistical methodologies to control for them.

The most effective methodology is randomisation. Randomisation attempts to create balanced groups at baseline, eliminating systematic differences. However, RCTs are sometimes not feasible because some factors cannot be allocated as part of interventions (e.g. marital status, gender, family members, smoking, alcohol consumption, use of drugs, accidents, etc.) or because RCTs are expensive, time-consuming, or raise ethical issues. Therefore, other strategies to control for confounders can be used in observational studies, including design (e.g. panel studies), selection methods (e.g. matching and restriction), and analytic methods (e.g. data stratification, statistical modelling, and instrumental variables) (Ajetunmobi 2002; Rothman et al. 2008). Advantages and disadvantages of each of these methods are briefly discussed.

Matching is a method performed at the beginning of a study and refers to the selection of pairs of participants with similar characteristics in terms of confounding (Ajetunmobi 2002). One of the pairs is 'treated', whereas the other is not (e.g. one of each pair would be asked to self-manage and the other not). Matching is potentially relevant for both observational studies and RCTs. Candidates for matching variables must be chosen carefully: if it is associated with the independent variable, there is a risk of overmatching leading to 'obscured' relationships between independent and dependent variables. Another limitation with matching is that matching variables cannot be used as possible 'risk factors' in the analysis. An example of a matching variable in this Thesis would be depression because depression is associated with both self-management and glycaemic control. It would be necessary to evaluate depression before recruitment to identify pairs of patients with the same level of depression. Overmatching would occur if the level of depression determined how well patients self-manage. Thus, matching in this study would be complex, time-consuming, and costly.

Restriction can be used to eliminate confounders using inclusion and exclusion criteria when selecting participants for a study (Ajetunmobi 2002). However, it is suggested to avoid over-restriction because it can threaten the external validity of the study as a result of a non-representative sample. This Thesis contains inclusion and exclusion criteria to eliminate confounders, e.g. included patients have one or more years with diabetes.

Stratification is the partition of the sampling frame into groups before sampling by a confounding factor (or analysing within each separately) (Ajetunmobi 2002). Stratifying the analysis based on confounders can confirm whether the potential confounder is affecting the study. However, a disadvantage of stratification is the reduction of sample size within strata leading to loss of statistical power.

Statistical modelling includes confounders in the model. The effect of any confounder is taken into account when determining the relationship(s) between the independent variable(s) and the dependent variable (Ajetunmobi 2002). I include demographic and clinical characteristics as confounders in regression models. However, not all confounders are known or measurable. The method of *instrumental variables* is a technique which controls for unknown and unmeasurable confounders.

When fitting regression models, problems are often encountered when one or more covariates are correlated with the error term. These covariates are called endogenous. This can happen if key covariates are missing from the model. By introducing an 'instrument' – a variable that does not directly affect the dependent variable only through its effect on the endogenous variable – a satisfactory model can still be obtained.

In observational studies, unmeasured confounders (U) are controlled using instrumental variables (Z) that are related to dependent variables (Y) only through their effect on independent variables (X) (Rothman et al. 2008).

Three assumptions for instrumental variables were described by Rothman et al. (2008). These assumptions can be described using an example of a published cohort study. The study examined the association between quality of care (X) and health-related quality of life (Y) using structure of care (Z) as an instrument to control unmeasured burden of illness (U) (Kahn et al. 2007). The assumptions are: i) the instrument (Z) affects the independent variable (X), (e.g. structure of care predicted better quality of care; ii) the instrument (Z) affects the dependent variable (Y) only through the effect on the independent variable (X) but not directly, e.g. structure of care indirectly affected better quality of life through the effect on better quality of care; and iii) the instrument (Z) and

the dependent variable (Y) share no common causes, e.g. other variables that cause quality of life should not have a causal relationship with structure of care.

Some limitations with instrumental variables include difficulties finding adequate instruments that meet the three assumptions or the use of weak instruments that have either a small direct effect on Y or an indirect effect on Y through other variables (other than X) (Martens et al. 2006). Martens et al. (2006) also suggests that an instrument can be biased in small samples when the regression model is complex and generates over-fitting (too many parameters in relation to the observations).

In this Thesis, there was a potential instrument for self-management, 'friends or relatives with diabetes'. Unmeasured confounders in this Thesis might have been controlled using 'friends or relatives with diabetes', because an argument could be made that the instrument would be related to HbA1c only through its effect on self-management. However, most patients in this study (95%, n=194) knew a friend or relative with diabetes. This made it impossible to use this variable as an instrument.

Cross-lagged panel designs can be used to identify the direction of causation, when two or more variables are repeatedly measured in a population over time and when the direction is uncertain, after 'ruling out' the hypothesis that their association is due to an unmeasured confounder (Campbell 1963; Kenny 1975). There are three types of correlation that can be explored in cross-lagged designs: cross-lagged correlations (rX_1Y_2 and rX_2Y_1), auto correlations (rX_1X_2 and rY_1Y_2), and synchronous correlations (rX_1Y_1 and rX_2Y_2) (Kenny 1975). Y refers to the effect, dependent variable, and X refers to the cause or independent variable. The effects of unmeasured confounders can be ruled out if two assumptions are satisfied: 1) synchronicity – X and Y are measured at the same point in time, and 2) stationarity – the strength and direction of the causes of a variable do not change over time. Stationarity can be assessed by consulting the synchronous correlations. Then, it is suggested that if X causes Y, the cross-lagged correlation of rX_1Y_2 would be higher than the cross-lagged correlation of rX_2Y_1 (Campbell 1963; Kenny 1975).

Cross-lagged correlations in panel designs have some limitations. Although, measuring both X and Y over time increases statistical power (Venter et al. 2002), these designs are costly and time-consuming. Rogosa (1980) notes that, even when the assumptions

are met, comparing the magnitude of the cross-lagged correlations may not be a sound basis for causal inference.

I planned to measure self-management, quality of care, and glycaemic control at both baseline and six-month follow-up, but home interviews were time-consuming and expensive and, therefore, beyond the resources of the project. Therefore, the analysis of cross-lagged correlations was not possible.

The ideal design to measure the relative importance of self-management and quality of care on glycaemic control would be a randomised 2 × 2 factorial trial. This design allows both the comparison of the effects of individual factors and their combination (Montgomery et al. 2003).

In such a factorial trial, there would be four groups: 1) both self-management and quality of care interventions, 2) self-management intervention only, 3) quality of care intervention only, and 4) control group receiving neither intervention. Using a regression model, one could adjust for the effect of each intervention, as well as control for confounders (and the dependent variable measured at baseline). The model would test the following comparisons: i) patients who received both interventions + patients who received self-management only vs. patients who received quality of care only + patients who did not receive any intervention, and ii) patients who received both interventions + patients who received quality of care only vs. patients who received self-management only + patients who did not receive any intervention. These 'contrasts' would show the average effect of the self-management intervention adjusted for the quality of care intervention, and vice-versa.

However, including all the proposed factors from this Thesis might not be feasible because some of the factors are potentially not good candidates for an intervention. For example, organisational issues might make it impossible to control continuity of care (e.g. by introducing temporary general practitioners). Another example could be the unethical assignment of patients to not receive treatment intensification when patients are not under glycaemic control.

10.3 The results in the context of the published literature

Few observational studies have measured both the individual contribution and relative importance of self-management and quality of care on glycaemic control in patients with type 2 diabetes (Parchman et al. 2002; O'Connor et al. 2004; Schmittdiel et al. 2008); see Chapter 6. I advance knowledge through including measures of various aspects of self-management and quality of care, and its evaluation of their individual contribution and relative importance in a longitudinal cohort study using regression modelling to control for confounders. This section answers the research questions proposed in this Thesis in Chapter 7 and puts each research question in the context of published literature.

> *RQ1. What are the demographic, clinical, self-management, and quality of care characteristics of patients with type 2 diabetes in primary care?*

The findings of the Thesis about rates of self-management behaviour and baseline measures of quality of care are similar to previous empirical literature using the same measurements in samples of Mexicans, Mexican-Americans, Latinos, or Hispanic patients with diabetes. Similar rates were found for diabetes knowledge, self-management behaviours, self-efficacy, continuity of care, and treatment intensification.

Studies using the DKQ-24 to measure diabetes knowledge reported similar average scores: 15.8 in this Thesis, and ranging from 13.2 to 17.3 in previous studies (Bustos-Saldaña et al. 2007; Garcia et al. 2001; Garcia 2008; Sixta and Ostwald 2008; Vincent et al. 2007). There were fewer patients with *strong* medical prescription knowledge in this Thesis (31.7%) than in a previous study using the same measure (51.6%) (Prado-Aguilar et al. 2009). Most of characteristics of the samples in both studies were similar but Prado-Aguilar et al. (2009) did not include patients with diabetes complications. Mean score of Diabetes Self-efficacy was similar to previous studies: 7.0 in this Thesis, and ranging from 6.2 to 7.5 in previous studies (Vincent et al. 2007; Lorig et al. 2008; Lorig et al. 2010). The findings from this Thesis about frequency of self-management behaviours were similar to Wen et al. (2004), Vincent et al. (2007), and Rosland et al. (2008). However, there was a large difference in the percentage of patients who did not participate in any specific exercise session between this Thesis and Wen et al. (2004) (87% vs. 38%, respectively). Patients were similar in both studies, but education level

was higher in the study by Wen et al. (2004), having 32.8% of patients with high school or more (17.5% in this Thesis). Vincent et al. (2007) and Rosland (2008) reported that patients were self-monitoring their blood glucose more frequently than patients in this Thesis. Recommendations of self-monitoring of blood glucose are more common for patients under insulin treatment (i.e. self-monitoring of blood glucose three or more times daily (ADA 2013)) than for patients under oral medications or diet and exercise. Rosland (2008) included patients under insulin, but Vincent et al. (2007) did not study this characteristic. I did not include patients taking insulin, and self-monitoring of blood glucose was not frequent. In Mexico, self-monitoring of blood glucose is an out-of-pocket expenditure for patients because healthcare institutions do not provide blood glucose meters. Some patients cannot afford this expenditure (44% of Mexicans are in poverty, see Chapter 2).

Mean score of the continuity of care index was similar to previous studies: 0.7 in this Thesis, 0.88 in Hispanics with type 2 diabetes from the Texas–Mexico border (Parchman et al. 2002), and 0.87 in patients with diabetes and enrolled in a national private health plan in the USA (Gill et al. 2003).

The percentage of patients undergoing treatment intensification was similar to previous empirical literature that used the same measure of treatment intensification but different samples: 58% in this Thesis in Mexican patients, 47% including patients from different ethnic groups (Caucasian, African-American, Asian, Pacific Islander, and Hispanic/Latino) (Schmittdiel et al. 2008), 56% including African-Americans patients who have shown difficulties controlling HbA1c levels (Selby et al. 2009), and from 54–57% in Dutch patients (van Bruggen et al. 2009). Other studies have reported different percentages of treatment intensification to this Thesis even using the same measure of treatment intensification (Ziemer et al. 2005; Katon et al. 2009). Ziemer et al. (2005) reported 32% of treatment intensification in a medical clinic and 65% in a diabetes clinic. The main difference between clinics was in terms of providers: internal medicine residents (medical clinic) and nurses or nurse-practitioners and an endocrinologist (diabetes clinic). Although I focused on GPs, the percentage of treatment intensification was closer to the percentage of treatment intensification reported in a diabetes clinic (Ziemer et al. 2005). Katon et al. (2009) found lower percentages of treatment intensification (39.6%) in mostly Caucasian patients with HbA1c levels ≥8%, and who were adherent with medication.

RQ2. What demographic and clinical factors are related to self-management and quality of care in primary care?

I examined demographic and clinical factors related to self-management behaviours, self-efficacy, diabetes knowledge, continuity of care, treatment intensification, patient–doctor communication, and patient satisfaction with diabetes care. The findings of this Thesis showed that a higher educational level was related to better diabetes knowledge, more self-management behaviours, higher self-efficacy, and higher continuity of care. It is possible that patients with higher educational level have more resources (i.e. information, time, or finances) to engage in self-management. A review concluded that higher education was related to healthy lifestyle behaviours and good health (Vlismas et al. 2009), but the review was not explicit about the search strategy, selection criteria, data collection, and analysis. Therefore, educational level as a potential predictor of self-management behaviours needs more research. Wong et al. (2008) reported that higher educational level was significantly related to good cardiovascular risk factor knowledge in adult patients (40 years and older) attending primary care. It has been suggested that patients whom physicians perceive to be 'intellectually capable' of understanding diabetes are more likely to be motivated to self-manage their condition (Lutfey et al. 2008). Younger patients also had better diabetes knowledge and this was reported previously (Sixta and Ostwald 2008) although the mean age and range was different. Sixta and Ostwald (2008) reported that the mean age was 56.3 ranging from 26 to 81 while the mean age in this Thesis was 60.8 ranging from 40 to 88.

Depression was associated with less self-management behaviour and this association has been reported previously (Ciechanowski et al. 2000; Egede and Osborn 2010; Gonzalez et al. 2007; Gonzalez et al. 2008). Although every study used a different instrument to assess depression, all evaluated depressive symptoms.

RQ3. What is the relationship within and between self-management and quality of care in primary care?

Previous empirical literature has reported relationships between self-efficacy and self-management behaviours (Rosland et al. 2008; Sousa et al. 2005; Wen et al. 2004). Wen (2004) found a significant relationship between self-management and self-efficacy in

Mexican American patients with type 2 diabetes. The study was focused on diet and exercise (for both self-managements and self-efficacy) using the SDSCA to measure self-management and the Multidimensional Diabetes Questionnaire to measure self-efficacy (Wen et al. 2004). Sousa et al. (2005) reported a significant relationship between self-management and self-efficacy in insulin-requiring patients with type 1 and type 2 diabetes. The measurements of both self-management and self-efficacy included a question about medication which was focused on insulin (Sousa et al. 2005). Rosland (2008) studied African-American and Latino patients with type 2 diabetes and measured self-management with the SDSCA and self-efficacy with the Perceived Competence for Diabetes scale. The significant relationship between self-management and self-efficacy has been reported regardless of population study, measurements, or self-management and self-efficacy focus (i.e. diet and exercise).

Parchman et al. (2002) used the same index of continuity of care to this Thesis but self-management was measured with stages of change for diabetes self-management (diet and exercise) by Parchman et al. (2002). Patients who advanced in stages of change for diet had higher levels in the index of continuity of care compared to the patients who did not advance (0.91 vs. 0.86, P 0.015). Although Parchman et al. (2002) reported a significant relationship between self-management and continuity of care, it is more difficult to compare with the results of this Thesis because self-management was measured differently. 'Stages of change' relates to a psychological concept (the intention to make changes to health behaviours). I measured self-management behaviours and did not find a relationship with the index of continuity of care.

Positive relationships between self-management and quality of care have been reported but using different measures of self-management and quality of care making it difficult to compare with the findings of this Thesis. For example, a relationship between self-management and quality of care has been reported previously using a proxy measure of self-management behaviours and process measures of quality of care (receipt of HbA1c test, eye examination, and nephropathy screening) (Heisler et al. 2003). Patients who rated their diabetes self-management more highly had more HbA1c tests, more eye examinations, and more nephropathy screening (Heisler et al. 2003).

RQ4. What demographic, clinical, self-management, and quality of care factors are related to glycaemic control at baseline in primary care?

Combination therapy (two or more oral antidiabetic medications) was related to higher levels of HbA1c in this Thesis. Although it would be expected that patients receiving more medications should have lower HbA1c levels, it is also possible that patients with monotherapy had good glycaemic control and therefore they did not need treatment intensification. Previous empirical literature found that patients without any medication were more likely to have HbA1c <7% (Kirk et al. 2010). However, Kirk et al. (2010) did not provide information about duration of diabetes, which suggests that patients might be recently diagnosed and treated with diet and exercise.

Patients in this Thesis who reported being satisfied with diabetes care had lower HbA1c levels at baseline, which was similar to a previous study (Chawla et al. 2010). This similarity should be viewed with some caution because the measurements of patient satisfaction were different in the two studies, and Chawla et al. (2010) did not test the validity and reliability of their satisfaction questionnaire. Satisfied patients with diabetes care might be more engaged in the management of their diabetes and therefore they are more likely to achieve good glycaemic control.

Continuity of care was not associated with HbA1c levels in this Thesis but previous cross-sectional studies have reported associations, although they are inconsistent. Some studies found that continuity of care was associated with lower HbA1c levels (Alazri and Neal 2003; Mainous et al. 2004). Other studies found no association between continuity of care and HbA1c (Overland et al. 2001; Sherina et al. 2003). One study showed that continuity of care was associated with higher HbA1c levels (Hanninen et al. 2001).

The inconsistency in the associations between continuity of care and HbA1c levels might be because there were also differences in the definition and measurement of continuity of care between these studies. Continuity of care is a contested term without a unique definition or measurement. I measured continuity of care as the frequency with which patients were seen by their usual GP. Alazri and Neal (2003) measured patients' satisfaction with continuity of care. Hanninen et al. (2001) asked whether patients had been seeing the same GP for at least 2 years. Mainous et al. (2004) measured whether patients had a usual source of care (site or provider). Overland et al. (2001) reported continuity of care as attending a single GP or being under the care of a GP for a greater

amount of time. Sherina et al. (2003) used an index of continuity of care which measured the number of visits to a usual provider. This variety of definitions and measurements makes it difficult to compare the results from studies that define and measure continuity of care differently.

RQ5. What demographic, clinical, self-management, and quality of care factors predict glycaemic control at six-month follow-up in primary care?

There were five factors related to HbA1c at six-month follow-up in univariate regression analysis: HbA1c at baseline, age, duration of diabetes, combination therapy, and treatment intensification. The relationship between HbA1c at baseline and follow-up has been reported by previous longitudinal studies (Karter et al. 2006; Nagrebetsky et al. 2012; Ng et al. 2005; O'Connor et al. 2004; Parchman et al. 2002).

It has been suggested that glycaemic control deteriorates over the years due to pancreatic β-cell dysfunction (Fonseca 2009; Marchetti et al. 2009) and therefore multiple therapies are required (Turner et al. 1999). This might be why patients with longer duration of diabetes had higher HbA1c levels and were under combination therapy. The lack of treatment intensification was also a predictor of high HbA1c levels. However, there was no association between treatment intensification and duration of diabetes. Although it has been suggested to use a less-stringent HbA1c <8% for glycaemic control in patients with longer duration of diabetes (ADA 2013), the MISS clinical guideline does not include this suggestion. Currie et al. (2010) also concluded that the minimum HbA1c target should be revised. For example, tight glycaemic control suggests that patients with more than 12 years of diabetes can have adverse effects from intensive glycaemic control (Skyler et al. 2009) and HbA1c targets should be less-stringent (ADA 2013).

The findings of this Thesis showed that none of the self-management predictors were associated with HbA1c at follow-up, and only treatment intensification as a quality of care predictor was associated to HbA1c at follow-up. The effect of treatment intensification agrees with previous empirical literature (Brown and Nichols 2003; Katon et al. 2009; Riddle et al. 2011; Schmittdiel et al. 2008; Sidorenkov et al. 2011).

Previous empirical literature has reported longitudinal associations between continuity of care and HbA1c. Some studies reported similar results to this Thesis with no association between continuity of care and HbA1c (Gulliford et al. 2007; Pereira et al. 2003) and others have found that continuity of care was associated with HbA1c (Parchman et al. 2002). Although Pereira et al. (2003) and Gulliford et al. (2007) showed similar results to this Thesis, continuity of care was measured differently because Pereira et al. (2003) used an index of physician's departure from the practice and Gulliford et al. (2007) used a questionnaire of experience continuity. Pereira et al. (2003) studied two groups of patients: those whose GPs left the practice and whose GPs remained in the practice. Pereira et al. (2003) compared the quality of care between these groups (departed versus GPs who remained) finding no significant difference in HbA1c between these groups. Gulliford et al. (2007) used a validated questionnaire of experienced continuity including four domains: longitudinal continuity, relational continuity, flexible continuity, and team and cross-boundary continuity (Gulliford et al. 2006). Longitudinal continuity was measured, asking patients about the frequency receiving care related to diabetes including a question about seeing their usual doctor or nurse but the association with HbA1c was analysed with the total score of the experienced continuity questionnaire (Gulliford et al. 2007). I measured continuity of care as the frequency that patients were seen by their usual GP using two methods (index of continuity of care from medical records and patients' report of this frequency). Parchman et al. (2002) used the same index of continuity of care to this Thesis reporting that higher scores on this index were significantly related to lower HbA1c levels ($r = -0.25$, $P < 0.001$). The association between continuity of care and HbAc1 was not found in this Thesis. Parchman (2002) reported higher score in the index of continuity of care (0.88 vs. 0.70 for this Thesis) and also used change in HbA1c as the dependent variable.

RQ6. What is the relative importance of self-management and quality of care in the prediction of glycaemic control at six-month follow-up in primary care?

Previous searches conducted as part of this Thesis found three studies including self-management and quality of care as predictors of HbA1c which have some similarities and differences to this Thesis.

Compared to Parchman et al. (2002), O'Connor et al. (2004), and Schmittdiel et al. (2008), I measured a wider range of self-management behaviours (diet, exercise, SMBG, avoiding tobacco, and taking medications) as well as more variables measuring quality of care (continuity of care, treatment intensification, patient–doctor communication, and patient satisfaction with diabetes care).

Parchman et al. (2002) included patients with type 2 diabetes from community health centres with similar characteristics to patients included in this Thesis in relation to age, gender, educational level, and diabetes duration. The design was similar (a cohort study), continuity of care was measured with the same index as this Thesis, and a regression model showed the individual contribution of self-management (advancement in stage of change) and continuity of care to HbA1c. Parchman et al. (2002) did not analyse the relative importance but analysed the mediation effect of advancement in stage of change for diet and exercise on the relationship between continuity of care and HbA1c, finding that advance in stages of change for diet mediated the relationship between continuity of care and HbA1c.

O'Connor et al. (2004) included patients with diabetes under the care of primary care providers. Age and duration of diabetes were similar in both studies but there were some differences because O'Connor et al. (2004) included fewer women, more college graduates, and more employed patients than this Thesis. The design was similar and both studies included multivariate models. However, O'Connor et al. (2004) did not use multivariate models to evaluate the relative importance but to control for confounders concluding that 'readiness to change' diabetes self-management was related to changes in HbA1c. The dependent variable was change in HbA1c at follow-up but analysis was restricted to patients with baseline HbA1c ≥7%. Including all patients could have allowed comparison of patients under good and poor glycaemic control. Although, the authors mentioned the assessment of the relationship between 'readiness to change' medication adherence and treatment intensification, details about this assessment were not provided and treatment intensification was measured by patient self-report (changes in diabetes medications in the past 12 months). Treatment intensification was defined and measured differently in this Thesis (increased dosage or medications extracted from medical records). O'Connor et al. (2004) specified that significant predictors in the initial analysis were included in the final model. It looks like O'Connor et al. (2004) did not include treatment intensification in the final model because it was not significant in

the initial analysis. The authors concluded that medication adherence (self-management behaviour) and readiness to change to diabetes self-management 'may be complementary but distinct domains' (O'Connor et al. 2004, p. 2328). Although O'Connor et al. (2004) does not explain the difference between medication adherence and readiness to change, the Transtheoretical Model (Conner and Norman 2005) explains that medication adherence is a behaviour, whereas 'readiness to change' relates to a psychological concept (the intention to make changes) rather than behaviours.

Schmittdiel et al. (2008) examined the relative importance of medication adherence and treatment intensification in patients with diabetes in a cross-sectional assessment. Patients were selected from a diabetes registry, and the assessment of both medication adherence and treatment intensification were from databases (n=122,967). Mean age was similar in Schmittdiel et al. (2008) and in this Thesis, but Schmittdiel et al. (2008) included fewer female patients, more patients with hypertension and just 11% were Hispanic/Latino. Schmittdiel et al. (2008) studied a cohort of patients but their analysis did not control for confounders. Schmittdiel et al. (2008) examined the relative importance of medication adherence and treatment intensification to HbA1c target (<7%). Schmittdiel et al. (2008) assessed medication adherence and treatment intensification from prescription databases and used the same method to measure treatment intensification as in this Thesis. The results showed that patients with both medication adherence and treatment intensification were more likely to achieve HbA1c <7% than patients who did not demonstrate either medication adherence or treatment intensification. The results were significant but as mentioned before, the analysis did not control for confounders. I found a significant relationship between treatment intensification and glycaemic control which was controlled for confounders in a regression model.

The previous section compares and contrasts the results of the cohort study reported in this Thesis, and previous studies using a similar design. The results of the current study found that self-management was not a predictor of HbA1c at follow-up. This may be surprising, as much evidence concerning the importance of self-management in HbA1c has been derived from experimental studies and assessments of the effects of the Chronic Care Model (Bodenheimer et al. 2002). The following section provides a summary of the effects of self-management interventions on behaviours, knowledge, self-efficacy, and glycaemic control from three reviews (Deakin et al. 2005; Norris et al.

2001; Sarkisian et al. 2003) and one meta-analysis of RCTs (Gary et al. 2003) that compared effects of interventions with control groups (Appendix 10.1, p. 415).

A third of studies reported effects of self-management interventions on glycaemic control compared with control groups (n=23, 37%). Eleven of those studies reported significant effects of these self-management interventions on self-management behaviours as well as on glycaemic control, 12 studies reported effects on self-management but no consequent effect on glycaemic control, and five studies reported the effects of self-management interventions on glycaemic control without demonstrating any effects on self-management (Agurs-Collins et al. 1997;D'Eramo-Melkus et al. 1992;Lo et al. 1996;Raz et al. 1988;Rickheim et al. 2002). This pattern of results suggests that self-management interventions are not consistent in improving glycaemic control, and that the effects of self-management interventions on glycaemic control are sometimes achieved without clear effects on self-management, which suggests that self-management interventions may achieve their effects through other mechanisms. Clearly, the role and impact of self-management varies, and the factors that determine that variation should be the focus of later study.

10.4 Interaction between treatment intensification and self-management behaviours

I included a secondary, exploratory analysis exploring interactions between core variables. The main research question was to evaluate the relative importance of self-management and quality of care to glycaemic control. The main hypothesis was that both factors would show a relationship with glycaemic control, and the aim was to explore their relative importance. However, in the context of the results described above, an exploratory secondary analysis was conducted which sought to assess whether the interaction of quality of care and self-management was associated with HbA1c. This might suggest a hypothesis to test in future primary research.

In the secondary analysis, I identified a significant interaction between self-management behaviours and treatment intensification showing that patients who did *not* receive treatment intensification (when treatment intensification was indicated) but reported more self-management behaviours had significantly lower HbA1c. This would suggest that self-management is important in patients who do not receive treatment

intensification when it is indicated. This finding needs further exploration because in the main analysis, treatment intensification was the most important predictor, and self-management was not a predictor of HbA1c levels.

Possible mechanisms for this interaction might be that GPs did not intensify treatment because they knew that patients were good self-managers and believed that good control could be achieved through patient self-management. This assumes that doctors are aware of their patients' self-management behaviour.

It has been suggested that doctors make treatment decisions based on combinations of patient non-medical characteristics which can predict the adherence to medical recommendations (Lutfey et al. 2008) and by experience with prior patients (Elstad et al. 2010). In patients with diabetes, Lutfey et al. (2008) concluded that 'physicians consistently made efforts to evaluate patients' capacities for understanding and taking care of their health outside of a medical context' (Lutfey et al. 2008, p. 11). Lutfey (2008) found that motivation and life style were two patient characteristics related to GP decision making in a vignette-based factorial experiment. These characteristics might be related to self-management behaviours (motivation to change lifestyle – i.e. diet and exercise). However, in both papers (Lutfey et al. 2008; Elstad et al. 2010), doctors made decisions based on a vignette (with an actor) and on their previous experience of managing patients of a similar profile. Therefore, the results were based on GP perceptions and presumptions of self-management behaviours of patients and it did not include any data collected directly from patients. Although both papers (Elstad et al. 2010; Lutfey et al. 2008) provide knowledge about interactions between patients and doctors, the results also might not be generalizable to the Mexican context. Mexico is an upper middle income country with half of the population in poverty compared to the countries included in Lutfey et al. (2008) and Elstad et al. (2010) which were high income countries (the USA, the UK and Germany). Von dem Knesebeck et al. (2010) reported a quantitative study highlighting that the healthcare system in each country is different (the USA, the UK and Germany) and there were also differences in the management of type 2 diabetes. This difference offers an opportunity to duplicate the study in the Mexican context and compare the findings to countries with different healthcare systems such as the USA, the UK and Germany.

It might be useful to explore interactions between patients and doctors in the process of decision making using a factorial experiment such as von dem Knesebeck et al. (2010) but including patients' views as well. A factorial experiment is a method to investigate the effects of two or more factors on an outcome variable.

10.5 Implications for policy and practice

10.5.1 Consultation length

As noted previously, the standard consultation for a diabetic patient in MISS is 15 minutes, which is longer than averages in other countries, and the impact of this on the results of the study need to be considered.

Consultation length has been related to a number of measures of quality of care (Campbell, J.L. et al. 2001;Campbell, S.M. et al. 2001;Freeman et al. 2002;Mercer and Howie 2006). Longer consultations have been related to less use of prescriptions (Freeman et al. 2002, Wilson and Childs 2002), higher prescribing quality (Wilson and Childs 2002), more lifestyle advice (Freeman et al. 2002), health promotion (Howie et al. 2004;Wilson and Childs 2002), better recognition and management of problems (Wilson and Childs 2002), and higher patient satisfaction (Wilson and Childs 2002).

In terms of quality of care, Campbell, S.M. et al. (2001) found that longer consultations were related to higher quality of clinical care and a higher probability of providing therapeutic interventions to improve glycaemic control (Campbell et al. 1999).

In terms of self-management, Freeman et al. (2002) found longer consultations allow the doctor to have time to offer more lifestyle advice. Wilson and Childs (2002) reviewed observational studies of consultation length in general practice finding evidence that longer consultations allow more time to offer health promotion and lifestyle advice.

GPs in MISS provide some level of health education and this is focused on treatment (medications, diet and exercise). Health education sessions at MISS have a traditional didactic approach where health professionals lead the sessions and they provide information about different aspects of diabetes. The aim of health education at MISS is

primarily to improve patients' knowledge about diabetes. Nearly half of the participants in this Thesis attended health education sessions before their participation in this study (43.4%) which is not that different from the 33% reported by Gonzalez-Zuñiga and Andrade-Islas (2000). These patients might have more knowledge about different aspects of diabetes but these patients may not have received interventions around self-efficacy and self-management, such as those provided in courses such as the Chronic Disease Self-Management Programmes (Stanford Patient Education Research Center 2013).

Overall, the literature would suggest that longer consultations improve quality of care and support for self-management. It is possible that longer consultations at MISS improve both aspects of care. Such an effect (increases in both self-management and quality of care) would not have a major impact on associations between these variables as measured in this study. However, it is possible that there is a tension between them. Kinmonth et al. (1998) found that delivery of a patient-centred intervention led to improvements in some aspects of care, but worse outcomes in clinical areas (such as weight and blood pressure). The authors concluded that

> 'Professionals committed to achieving the benefits of patient centred consulting should take care not to lose the focus on disease while paying attention to the unique experience of illness of each patient' (Kinmonth et al. 1998, p. 1208).

In summary, longer consultations would be expected to lead to better performance on both self-management and quality of care, which should not have a major impact on associations between these variables. There is limited evidence that improvements in one area (for example, greater attention to self-management) may be related to worse performance on clinical measures).

10.5.2 Treatment intensification

I found that GPs did not intensify medical treatment in half of the patients for whom it was indicated. The reasons why GPs did not intensify medical treatment were not explored in this Thesis. However, previous studies reported that patients receive half of the recommended processes of care (54.9%) including preventive, acute and chronic care (McGlynn et al. 2003). In this study, patients with diabetes received 45.4% of

recommended processes of care including 13 indicators e.g. diet and exercise counselling (McGlynn et al. 2003). Shrank et al. (2006) reported that participants received 61.9% of recommended medical treatment and appropriate medications were prescribed 62.6% of the time. Although the studies of McGlynn and Shrank were performed in the USA, Mexico performed similarly to a mix of low middle income, upper middle income, and high income countries in a measured of health system performance by WHO (WHO 2000).

Treatment intensification was a quality of care predictor but the lack of treatment intensification may reflect concerns that rigorous attempts to reduce HbA1c can be harmful. Treatment intensification is a complex issue because the HbA1c target is contested. Recent RCTs have shown that the usual HbA1c target (HbA1c <7.0%) can be harmful in selected patients (i.e long duration of diabetes and risk of cardiovascular disease). The issue of HbA1c targets has not been discussed in the most recent update of the MISS clinical practice guideline. Clinical practice could be improved if both treatment intensification and HbA1c targets were included in a future update of MISS clinical practice guideline. This update should also be implemented nationally through the Secretary of Health which is the highest authority in Mexico in terms of healthcare.

10.5.3 Quality improvement

Boaden et al. (2008) presented different approaches to improve quality of care: the Plan-Do-Study-Act model, Statistical Process Control, Six Sigma, Lean, Theory of Constraints, and Mass Customisation. The focus of these approaches is the process of care and its variation, the flow in the provision of care, and the needs of the 'customer' (customers can be patients, GPs, other providers, etc.). Boaden et al. (2008) also suggest that healthcare services are part of complex structures and this complexity will depend on the context where healthcare is provided. For example, management of type 2 diabetes was different in three high income countries (the USA, the UK and Germany) which might relate to differences in the healthcare system in each country (von dem Knesebeck et al. 2010).

In Mexico, healthcare services are provided by a range of institutions compared to the UK where health services are mainly provided by the National Health Service (see Chapter 3). It might be easier to implement a primary care quality improvement in a

specific institution like MISS where primary care delivers approximately 85% of all health services and healthcare is standardised in terms of structure (e.g. similar facilities and primary care providers) and process of care (e.g. provision of preventive, diagnostic and curative care).

An attempt to improve quality of diabetes primary care was recently published (Barcelo et al. 2010). This was a pilot study using the Chronic Care Model by Wagner in 1999 and the Chronic Illness Breakthrough Series by the Institute for Healthcare Improvement in 2001 (Wagner et al. 1999; Wagner et al. 2001). Ten primary care practices implemented a clinical information system and patients were offered HbA1c and lipid tests at baseline and at the end of the study. Five of the practices were randomly selected to receive the intervention and the other five practices continued with usual care. There is no information about allocation. All practices also provided peer support groups for patients. Health providers from the intervention practices identified areas for improvement using the Chronic Care Model: organisation of care, community linkages, self-management support, delivery system design, decision support, and clinical information system. Teams in the intervention centres received three learning sessions to implement strategies to improve quality of diabetes care. Current referral systems changed as part of the intervention, bringing specialists to primary care centres where patients were seen by a health team. There was also a case manager advisor for patients who were not achieving goals (HbA1c <7%, cholesterol <200 mg/dl, blood pressure <140/90, food and eye examinations performed). These goals were the outcomes. There were 196 patients in the intervention group and 111 in the control group. Intervention group patients improved goals significantly more than control group (HbA1c, cholesterol, and patients receiving foot and eye examinations). There were some activities delivered in both intervention and control groups (clinical information system and peer support groups) as well as contamination between practices because of the local publicity of the intervention (Barcelo et al. 2010). However, Barcelo et al. (2010) showed that it is possible to implement quality improvement in Mexico. Although Barcelo et al. (2010) did not include MISS primary care practices, Barcelo et al.'s study was focused on primary care and it may be possible to duplicate the study into the MISS context.

Mexican GPs receive a salary and there is no incentive system for meeting targets in the provision of healthcare services such as diabetes care (e.g. HbA1c targets to achieve

glycaemic control). A pay-for-performance scheme could be implemented to improve diabetes primary care in Mexico. For example, an indicator about achievement of glycaemic control could be developed including specific HbA1c targets based on patient's characteristics e.g. 'less-stringent target' (HbA1c <8%) for patients <60 years and with a history of severe hypoglycaemia, limited life expectancy, diabetic complications, multiple comorbidities, and long-standing diabetes (ADA 2013).

There is some evidence that incentives lead to modest improvements in processes and outcomes (Gillam et al. 2012;Ryan and Doran 2012). For example, 29.6% change in diabetes outcomes were attributable to change in processes of diabetes care including HbA1c measured (process) and HbA1c controlled (outcome). However, some evidence of the effectiveness of pay for performance on quality of care is not compelling (Flodgren et al. 2011;Scott et al. 2011). For example, Scott et al. (2011) found that six of the seven studies included in their review 'showed positive but modest effects on a minority of the measures of quality of care included in the study' (Scott et al. 2011, p. 21).

There is also a risk of dual agenda of addressing the needs of the patient and the focus of the indicator (Campbell et al. 2008). An example from this Thesis might be that doctors would intensify medications in patients with diabetes when it may not be indicated. Another limitation of an incentive scheme may be unintended consequences of focusing on hitting a target associated with an indicator (Campbell et al. 2011;Lester et al. 2011). For example, practice staff perceived that the indicator of palliative care could be potentially harmful to patients. Therefore, it was highlighted the importance of piloting quality of care indicators as part of incentive schemes (Campbell et al. 2011;Lester et al. 2011). The implementation of an incentive scheme within the Mexican primary care context should be piloted first to identify unintended consequence.

10.5.4 Self-management and treatment intensification

If the interaction between self-management behaviours and treatment intensification demonstrated in this secondary analysis was confirmed in further research, it suggests that in patients where treatment intensification does not occur (especially where GPs consider that it is inappropriate, or where patients have objections to the use of

medication, self-management might be improved by referring such patients to an evidence based programme like the Diabetes Self-Management Program from the Stanford Patient Education Research Centre (Stanford Patient Education Research Center 2012) or the ¡Viva bien! programme (Toobert et al. 2011). However, Foster et al. (2007) reported that lay-led self-management interventions, like the self-management programmes from the Stanford Patient Education Research Centre, did not show any significant effects on improving the HbA1c levels in people with diabetes. The ¡Viva bien! programme included female Latinos with type 2 diabetes (from Latin American countries including Mexico) and it was adapted culturally from a previous programme called the Mediterranean Lifestyle Program (Osuna et al. 2011). The Mediterranean Lifestyle Program was effective in improving self-management behaviours such as diet, exercise, stress management, and weight loss (Toobert et al. 2005). Successful self-management programmes could be culturally adapted into the Mexican context of primary care following the adaptation stages suggested by Osuna et al. (2011).

10.6 Implications for research

The findings from this Thesis suggest potential studies for future research.

Problems with recruitment meant that the current study may not have had sufficient power to detect important relationships. Future research could replicate this study but increasing the sample size and using additional strategies to recruit more potential participants (i.e. home visits to explain the research project) as well as extending the follow-up. It is possible that the effects of self-management and quality of care are only apparent in the longer term.

A more sophisticated measure of treatment intensification could be used, taking into account patient characteristics (history of hypoglycaemia, diabetes duration, age, diabetes complications, comorbidities, cardiovascular disease, and cardiovascular risk factors) as well as different HbA1c target for every patient, as suggested by ADA (2012), Gerstein et al. (2008), and Inzucchi et al. (2012) in Chapter 4. HbA1c was the only outcome in this Thesis because there were not enough resources to do more interviews at six months. It is possible that self-management and quality of care make a difference to other patient-related outcomes such as quality of care, patient-doctor

communication and patient satisfaction. Future research could include secondary outcomes like these patient-related outcomes.

Future research could also use more advanced designs such as a cross-lagged panel or including instrumental variables, to better control for the effects of confounders as well as factorial experiments to assess the relative contribution of self-management and quality of care interventions.

The findings from this Thesis suggest that treatment intensification could be the focus of an intervention to improve HbA1c. However, such an intervention should take into account the complexities of primary healthcare and individual patients (Greenhalgh and Heath 2010a; Greenhalgh and Heath 2010b; Heath et al. 2007). An intervention in shared decision making could involve both GPs and patients. This intervention would take into account the complexities mentioned above. Elwyn (2012b) suggested using 'option grids' in shared decision making research. These option grids include a summary of options about a specific decision related to patients care. In a study of shared decision making for treatment intensification, the option grid would include information about patients characteristics related to specific HbA1c targets (ADA 2013; Gerstein et al. 2008; Inzucchi et al. 2012) and the potential diabetes management to achieve the target as well as benefits and side effects of every diabetes management option. This option grid would be useful for both GPs and patients. While patients would be involved in making decisions, GPs would have a useful tool to take into account the complexities of treatment intensification. Option grids have been implemented recently and there is not available evidence of their effectiveness but other decision aids have shown improvements in patient knowledge (O'Connor et al. 2009).

Further discrete choice experiments could be conducted to elicit preferences between quality of care and self-management support. The discrete choice experiment could estimate whether patients prefer that GPs focus on disease management or whether patients would like to trade-off against greater self-management support. A qualitative study would be needed to choose the attributes and levels in such a discrete choice experiment of trade-offs between disease management and self-management support (Ryan and Farrar 2000).

10.7 Conclusion

This PhD has provided an assessment of various measures of both self-management and quality of care in patients with type 2 diabetes, and an evaluation of their individual contribution and relative importance in a longitudinal cohort in Mexican primary care settings.

Treatment intensification was the main predictor of lower HbA1c levels at follow-up suggesting that quality of care (treatment intensification) was more important than self-management as a predictor of glycaemic control, at least in the context of Mexican primary care. Although none of the self-management predictors was significantly related to HbA1c, an exploratory interaction showed that patients who did not receive treatment intensification when they needed it and performed more self-management behaviours had lower HbA1c levels at follow-up.

References

Aboulghate, A., Abel, G., Elliott, M.N., Parker, R.A., Campbell, J., Lyratzopoulos, G., & Roland, M. 2012. Do English patients want continuity of care, and do they receive it? *British Journal of General Practice*, 62, (601) 567–575.

ADA 2013. Standards of Medical Care in Diabetes--2013. *Diabetes Care*, 36, (Supplement 1) S11-S66.

Agurs-Collins, T.D., Kumanyika, S.K., Ten Have, T.R., & ms-Campbell, L.L. 1997. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. *Diabetes Care*, 20, (10) 1503-1511.

Aiken, L.S. & West, S.G. 1991. *Multiple regression: testing and interpreting interactions* California, USA, Sage Publications, Inc.

Ajetunmobi, O. 2002. *Making sense of critical appraisal* London, Arnold.

Alazri, M.H. & Neal, R.D. 2003. The association between satisfaction with services provided in primary care and outcomes in Type 2 diabetes mellitus. *Diabetic Medicine*, 20, (6) 486–490.

Ali, S., Stone, M.A., Peters, J.L., Davies, M.J., & Khunti, K. 2006. The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis. *Diabetic Medicine*, 23, (11) 1165–1173.

Alonso, A., Segui-Gomez, M., de, I.J., Sanchez-Villegas, A., Beunza, J.J., & Martinez-Gonzalez, M.A. 2006. Predictors of follow-up and assessment of selection bias from dropouts using inverse probability weighting in a cohort of university graduates. *European journal of epidemiology*, 21, (5) 351–358.

Altman, D.G. 1991. *Practical statistics for medical research* London, Chapman & Hall.

Altman, D.G. 2000. Statistics in medical journals: some recent trends. *Statistics in Medicine*, 19, (23) 3275–3289 available from: PM:11113959.

AMA. H-450.975 Definition of quality. https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl. 2012. American Medical Association. 30-7-2012.

Amador-Diaz, M.B., Marquez-Celedonio, F.G., & Sabido-Sighler, A.S. 2007. [Self Healthcare-associated Factors in Patients with Type 2 Diabetes Mellitus]. *Archivos en Medicina Familiar*, 9, (2) 99–107.

Amiel, S.A., Dixon, T., Mann, R., & Jameson, K. 2008. Hypoglycaemia in Type 2 diabetes. *Diabetic Medicine*, 25, (3) 245–254.

Anderson, R.M., Funnell, M.M., Fitzgerald, J.T., & Marrero, D.G. 2000. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care*, 23, (6) 739–743.

Anderson, R.T., Balkrishnan, R., Camacho, F., Bell, R., Duren-Winfield, V., & Goff, D. 2003. Patient-centered outcomes of diabetes self-care. Associations with satisfaction

and general health in a community clinic setting. *North Carolina Medical Journal*, 64, (2) 58–65.

Arah, O.A., Westert, G.P., Hurst, J., & Klazinga, N.S. 2006. A conceptual framework for the OECD Healthcare Quality Indicators Project. *International Journal for Quality in Health Care*, 18 Suppl. 1, 5–13.

Arcega-Dominguez, A. & Celada-Ramirez, N.A. 2008. Control de pacientes con diabetes. (Spanish). *Revista Medica del Instituto Mexicano del Seguro Social*, 46, (6) 685-690.

Avery, A.J., Dex, G.M., Mulvaney, C., Serumaga, B., Spencer, R., Lester, H.E., & Campbell, S.M. 2011. Development of prescribing-safety indicators for GPs using the RAND Appropriateness Method. *British Journal of General Practice*, 61, (589) e526-e536.

Avorn, J. & Fischer, M. 2010. 'Bench to behavior': translating comparative effectiveness research into improved clinical practice. *Health Affairs (Millwood.)*, 29, (10) 1891–1900.

Baker, R., Boulton, M., Windridge, K., Tarrant, C., Bankart, J., & Freeman, G.K. 2007. Interpersonal continuity of care: a cross-sectional survey of primary care patients' preferences and their experiences. *British Journal of General Practice*, 57, (537) 283–289.

Baker, R., Freeman, G., Boulton, M., Windridge, K., Tarrant, C., Low, J., Turner, D., Hutton, E., & Bryan, S. 2001, *Continuity of care: patients' and carers' views and choices in their use of primary care services. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO).*

Bandura, A. 1997a. *Self-Efficacy in Changing Societies* Cambridge University Press.

Bandura, A. 1997b. *Self-efficacy : the exercise of control* New York : W.H. Freeman.

Barcelo, A., Cafiero, E., de, B.M., Mesa, A.E., Lopez, M.G., Jimenez, R.A., Esqueda, A.L., Martinez, J.A., Holguin, E.M., Meiners, M., Bonfil, G.M., Ramirez, S.N., Flores, E.P., & Robles, S. 2010. Using collaborative learning to improve diabetes care and outcomes: the VIDA project. *Primary Care Diabetes*, 4, (3) 145–153.

Barlow, J., Wright, C., Sheasby, J., Turner, A., & Hainsworth, J. 2002. Self-management approaches for people with chronic conditions: a review. *Patient Education and Counseling*, 48, (2) 177–187.

Bayliss, E.A., Ellis, J.L., & Steiner, J.F. 2007. Barriers to self-management and quality-of-life outcomes in seniors with multimorbidities. *Annals of Family Medicine*, 5, (5) 395–402.

Bebb, C., Kendrick, D., Stewart, J., Coupland, C., Madeley, R., Brown, K., Burden, R., & Sturrock, N. 2005. Inequalities in glycaemic control in patients with Type 2 diabetes in primary care. *Diabetic Medicine*, 22, (10) 1364–1371.

Beck, A.T., Steer, R.A., & Garbin, M.G. 1988. Psychometric Properties of the Beck Depression Inventory – 25 Years of Evaluation. *Clinical Psychology Review*, 8, (1) 77–100.

Benachi Sandoval, N., Castillo Martinez, A., Vilaseca Llobet, J.M., Torres Belmonte, S., & Risco Vilarasau, E. 2012. Validacion de la version en español del cuestionario PCAS para evaluar la atencion primaria de salud. *Revista Panamericana de Salud Publica*, 31, 32–39.

Bertakis, K.D., Azari, R., Helms, L.J., Callahan, E.J., & Robbins, J.A. 2000. Gender differences in the utilization of healthcare services. *Journal of Family Practice.*, 49, (2) 147–152.

Bland, M. 2000. *An introduction to medical statistics, 3rd ed* Oxford, Oxford University Press.

Blaum, C.S., Velez, L., Hiss, R.G., & Halter, J.B. 1997. Characteristics related to poor glycemic control in NIDDM patients in community practice. *Diabetes Care,* 20, (1) 7–11.

Boaden, R., Harvey, G., Moxham, C., & Proudlove, N. 2008, *Quality improvement: Theory and practice in health care*, NIHR, London.

Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. 2002. Patient self-management of chronic disease in primary care. *Journal of the American Medical Association*, 288, (19) 2469–2475.

Boyle, S. 2011. United Kingdom (England): Health system review. *Health Systems in Transition*, 13, (1) 1–483, xix–xx.

Bradley, C. 1994. *Handbook of psychology and diabetes* Hardwood Academic Publishers.

Brook, R.H., McGlynn, E.A., & Shekelle, P.G. 2000. Defining and measuring quality of care: a perspective from US researchers. *International Journal for Quality in Health Care*, 12, (4) 281–295.

Brown, J.B. & Nichols, G.A. 2003. Slow response to loss of glycemic control in type 2 diabetes mellitus. *American Journal of Managed Care*, 9, (3) 213–217.

Bruner, D.W., Movsas, B., Konski, A., Roach, M., Bondy, M., Scarintino, C., Scott, C., & Curran, W. 2004. Outcomes research in cancer clinical trial cooperative groups: the RTOG model. *Quality of Life Research*, 13, (6) 1025–1041.

Buetow, S. 1998. Four strategies for negotiated care. *Journal of the Royal Society of Medicine*, 91, (4) 199.

Buetow, S. 2011. Person-centred care: Bridging current models of the clinician-patient relationship. *International Journal of Person Centered Medicine;* 1, (1) 196–203.

Burke, N.J., Bird, J.A., Clark, M.A., Rakowski, W., Guerra, C., Barker, J.C., & Pasick, R.J. 2009. Social and cultural meanings of self-efficacy. *Health Education &.Behavior*, 36, (5 Suppl) 111S-128S.

Bustos-Saldaña, R., Barajas-Martinez, A., Lopez-Hernandez, G., Sanchez-Novoa, E., Palomera-Palacios, R., & Islas-Garcia, J. 2007. [Knowledge on Diabetes Mellitus in Urban and Rural Patients with Type 2 Diabetes Mellitus from Western Mexico]. *Archivos en Medicina Familiar*, 9, (3) 147–159.

Cameron, M.A. & Falleti, T.G. 2005. Federalism and the Subnational Separation of Powers. *Publius: The Journal of Federalism*, 35, (2) 245–271.

Campbell, D. T. 1963, "From description to experimentation: interpreting trends as quasi-experiments," *In Problems in measuring change*, C. W. Harris, ed., Madison, Wis: University of Wisconsin Press.

Campbell, J.L., Ramsay, J., & Green, J. 2001. Practice size: impact on consultation length, workload, and patient assessment of care. *British Journal of General Practice*, 51, (469) 644-650.

Campbell, S.M. & Eriksson, T. 2011. Multiple strategies for quality improvement and patient safety-money alone is not the answer, nor is trust. Conclusions of the 6th EQuiP Invitational conference April 2011. *European Journal of General Practice.*, 17, (4) 238–240.

Campbell, S.M., Hann, M., Hacker, J., Burns, C., Oliver, D., Thapar, A., Mead, N., Safran, D.G., & Roland, M.O. 2001. Identifying predictors of high quality care in English general practice: observational study. *Britsh Medical Journal*, 323, (7316) 784-787.

Campbell, S.M., Kontopantelis, E., Hannon, K., Burke, M., Barber, A., & Lester, H.E. 2011. Framework and indicator testing protocol for developing and piloting quality indicators for the UK quality and outcomes framework. BMC Family Practice, 12, 85.

Campbell, S.M., McDonald, R., & Lester, H. 2008. The experience of pay for performance in English family practice: a qualitative study. Annals of Family Medicine, 6, (3) 228-234.

Campbell, S.M., Roland, M.O., & Buetow, S.A. 2000. Defining quality of care. *Social Science & Medicine*, 51, (11) 1611–1625.

Campbell, S.M., Roland, M.O., Shekelle, P.G., Cantrill, J.A., Buetow, S.A., & Cragg, D.K. 1999. Development of review criteria for assessing the quality of management of stable angina, adult asthma, and non-insulin dependent diabetes mellitus in general practice. *Quality in Health Care*, 8, (1) 6-15.

Canal del Congreso. Proceso legislativo. http://www.canaldelcongreso.gob.mx/nueva_imagen/seccion.php?id=42 2011 12-7-2012.

Castro-Rios, A., Coria-Soto, I., Mould-Quevedo, J., Asbun-Alvarez, M., Valdespino-Vazquez, R., Hernandez-Elizarraras, H., & Garduño-Espinosa, J. 2005, 'Evaluation of the family medicine improvement process,' *In Family medicine at the dawn of the 21st century. Themes and arguments*, C. Garcia-Peña et al., eds., Mexico, D.F.: Instituto Mexicano del Seguro Social, pp. 253–276.

CDC. Epi Info™ 6. [Epi Info™ 6.04d]. 2001. Atlanta, USA, Centers for Disease Control and Prevention.

Chawla, A., Saha, C., & Marrero, D.G. 2010. A novel application of the Problem Areas in Diabetes (PAID) instrument to improve glycemic control and patient satisfaction. *Diabetes Educator*, 36, (2) 337–344.

Cheraghi-Sohi, S., Bower, P., Mead, N., McDonald, R., Whalley, D., & Roland, M. 2007. Making sense of patient priorities: applying discrete choice methods in primary care using 'think aloud' technique. *Family Practice*, 24, (3) 276–282.

Cheraghi-Sohi, S., Hole, A.R., Mead, N., McDonald, R., Whalley, D., Bower, P., & Roland, M. 2008. What patients want from primary care consultations: a discrete choice experiment to identify patients' priorities. *Annals of Family Medicine*, 6, (2) 107–115.

Ciechanowski, P.S., Katon, W.J., & Russo, J.E. 2000. Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Archives of Internal Medicine.*, 160, (21) 3278–3285.

Clark, M. 2008. Diabetes self-management education: a review of published studies. *Primary Care Diabetes*, 2, (3) 113–120.

Clark, N.M., Janz, N.K., Dodge, J.A., & Sharpe, P.A. 1992. Self-regulation of health behavior: the 'take PRIDE' program. *Health Education Quarterly*, 19, (3) 341–354.

Clark, N.M., Becker, M.H., Janz, N.K., Lorig, K., Rakowski, W., & Anderson, L. 1991. Self-Management of Chronic Disease by Older Adults: A Review and Questions for Research. *Journal of Aging and Health*, 3, (1) 3–27.

Cole, S.A. & Bird, J. 2000. *The medical interview: the three-function approach, 2nd ed* St. Louis, Mo, Mosby.

Colman, A.M. 2006. *A dictionary of psychology, 2nd ed* Oxford, Oxford University Press.

Committee on the Crossing the Quality Chasm: Next Steps Toward 2004. *1st Annual Crossing the Quality Chasm Summit: A Focus on Communities* The National Academies Press.

Compean Ortiz, L.G., Gallegos Cabriales, E.C., Gonzalez Gonzalez, J.G., & Gomez Meza, M.V. 2010. Self-care behaviors and health indicators in adults with type 2 diabetes. *Revista Latino-Americana de Enfermagem*, 18, (4) 675–680.

CONEVAL. Anexo estadistico – Pobreza 2010. Anexo estadistico. http://www.coneval.gob.mx/cmsconeval/rw/pages/medicion/Pobreza_2010/Anexo_estadistico.es.do 2010. 12-7-2012.

CONEVAL. Anexo estadistico – Pobreza 2010. Mapas. http://www.coneval.gob.mx/cmsconeval/rw/pages/medicion/Pobreza_2010/Anexo_estadistico.es.do 2011. 12-7-2012.

CONEVAL. Glossary. http://www.coneval.gob.mx/cmsconeval/rw/pages/medicion/glosario.en.do 11-7-2012. 11–7-2012.

Conner, M. & Norman, P. 2005, 'Predicting health behaviour: a social cognition approach,' *In Predicting health behaviour: research and practice with social cognition models*, M. Conner & P. Norman, eds., Maidenhead, England: Open University Press, pp. 1–27.

Cook, C.B., Ziemer, D.C., El-Kebbi, I.M., Gallina, D.L., Dunbar, V.G., Ernst, K.L., & Phillips, L.S. 1999. Diabetes in urban African-Americans. XVI. Overcoming clinical inertia improves glycemic control in patients with type 2 diabetes. *Diabetes Care*, 22, (9) 1494–1500.

Corben, S. & Rosen, R. 2005, *Self-management for long-term conditions*, King's Fund, London.

Coulter, A., Edwards, A., Elwyn, G., & Thomson, R. 2011. Implementing shared decision making in the UK. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*, 105, (4) 300–304.

Cryer, P.E. 2009. Preventing hypoglycaemia: what is the appropriate glucose alert value? *Diabetologia*, 52, (1) 35–37.

Currie, C.J., Peters, J.R., Tynan, A., Evans, M., Heine, R.J., Bracco, O.L., Zagar, T., & Poole, C.D. 2010. Survival as a function of HbA(1c) in people with type 2 diabetes: a retrospective cohort study. *Lancet*, 375, (9713) 481-489.

D'Eramo-Melkus, G.A., Wylie-Rosett, J., & Hagan, J.A. 1992. Metabolic impact of education in NIDDM. *Diabetes Care*, 15, (7) 864-869.

Dasgupta, K., Chan, C., Da, C.D., Pilote, L., De, C.M., Ross, N., Strachan, I., Sigal, R., & Joseph, L. 2007. Walking behaviour and glycemic control in type 2 diabetes: seasonal and gender differences–study design and methods. *Cardiovascular Diabetology*, 6, 1.

Dattalo, P. 2008. *Determining sample size: balancing power, precision, and practicality* Oxford; New York: Oxford University Press.

Davis, W.A., Bruce, D.G., & Davis, T.M. 2006. Is self-monitoring of blood glucose appropriate for all type 2 diabetic patients? The Fremantle Diabetes Study. *Diabetes Care*, 29, (8) 1764–1770.

de Koning, J.S., Klazinga, N.S., Koudstaal, P.J., Prins, A., Borsboom, G.J., & Mackenbach, J.P. 2005. The role of 'confounding by indication' in assessing the effect of quality of care on disease outcomes in general practice: results of a case-control study. *BMC Health Services Research*, 5, (1) 10.

de-Haes, H. 2006. Dilemmas in patient centeredness and shared decision making: a case for vulnerability. Patient Educ.Couns., 62, (3) 291-298.

Deakin, T., McShane, C.E., Cade, J.E., & Williams, R.D. 2005. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews*, (2) CD003417.

DeFriese, G.H., Woomert, A., Guild, P.A., Steckler, A.B., & Konrad, T.R. 1989. From activated patient to pacified activist: a study of the self-care movement in the United States. *Social Science & Medicine*, 29, (2) 195–204.

Del Castillo Arreola, A., Guzman-Saldana, R.M.E., Iglesias-Hoyos, S., & Reyes-Lagunes, I. 2012. Divergent and convergent validity of the Diabetes Treatment Self-Efficacy instrument. *Psicologia Iberoamericana*, 20, (2) 58-65.

Delgado-Rodriguez, M. & Llorca, J. 2004. Bias. *Journal of Epidemiology and Community Health*, 58, (8) 635–641.

den Boer, P.C., Wiersma, D., & Van den Bosch, R.J. 2004. Why is self-help neglected in the treatment of emotional disorders? A meta-analysis. *Psychological Medicine,* 34, (6) 959–971.

Department of Health. *Self care – a real choice: self care support – a practical option.* London; 2005.

Derbez-del-Pino, M., Martinez-Hernandez, C., Garcia-Valerio, Y., & Garcia-Nieto, H. U. 2005, 'The electronic record and the family medicine information system,' *In Family medicine at the dawn of the 21st century. Themes and arguments*, C. Garcia-Peña et al., eds., Mexico, D.F.: Instituto Mexicano del Seguro Social, pp. 109–131.

Deveugele, M., Derese, A., Brink-Muinen, A., Bensing, J., & De, M.J. 2002. Consultation length in general practice: cross sectional study in six European countries. *British Medical Journal*, 325, (7362) 472.

Diabetes UK. HbA1c Standardisation. For clinical healthcare profesionals. http://www.diabetes.org.uk/upload/Professionals/Key%20leaflets/53130HbA1cHCPleaflet.pdf 2011. 19-7-2012.

Diabetes UK. Healthy lifestyles. http://www.diabetes.org.uk/Guide-to-diabetes/Healthy_lifestyle/ 2012. 30-7-2012.

Diaz-Apodaca, B.A., de Cosio, F.G., Canela-Soler, J., Ruiz-Holguin, R., & Cerqueira, M.T. 2010. Quality of diabetes care: a cross-sectional study of adults of Hispanic origin across and along the United States–Mexico border. *Revista Panamericana de Salud Pública*, 28, (3) 207–213.

Dixon, J.B. 2009. Obesity and diabetes: the impact of bariatric surgery on type-2 diabetes. *World Journal of Surgery*, 33, (10) 2014–2021.

Dolovich, L.R., Nair, K.M., Ciliska, D.K., Lee, H.N., Birch, S., Gafni, A., & Hunt, D.L. 2004. The Diabetes Continuity of Care Scale: the development and initial evaluation of a questionnaire that measures continuity of care from the patient perspective. *Health & Social Care in the Community*, 12, (6) 475–487.

Donabedian, A. 1966. Evaluating the quality of medical care. *Milbank Memorial Fund Quarterly*, 44, (3) Suppl-206.

Donabedian, A. 1990. The seven pillars of quality. *Archives of Pathology & Laboratory Medicine*, 114, (11) 1115–1118.

Donabedian, A. 1980. *Explorations in quality assessment and monitoring; Vol.1, The definition of quality and approaches to its assessment* Ann Arbor, Michigan, Health Administration Press.

Drury, P. & Gatling, W. 2005. *Diabetes* London, UK, Elsevier Limited.

Duke, S.A., Colagiuri, S., & Colagiuri, R. 2009. Individual patient education for people with type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews*, (1) CD005268.

Dupont, W.D. 2009. *Statistical modeling for biomedical researchers: a simple introduction to the analysis of complex data*, *2nd ed* Cambridge University Press.

Efron, B. & Tibshirani, R.J. 1993. *An introduction to the bootstrap* New York, Chapman & Hall.

Egede, L.E. 2007. Major depression in individuals with chronic medical disorders: prevalence, correlates and association with health resource utilization, lost productivity and functional disability. *General Hospital Psychiatry*, 29, (5) 409–416.

Egede, L.E., Ellis, C., & Grubaugh, A.L. 2009. The effect of depression on self-care behaviors and quality of care in a national sample of adults with diabetes. *General Hospital Psychiatry*, 31, (5) 422–427.

Egede, L.E. & Osborn, C.Y. 2010. Role of motivation in the relationship between depression, self-care, and glycemic control in adults with type 2 diabetes. *Diabetes Educator*, 36, (2) 276–283.

Egger, M., Smith, G. D., & Schneider, M. 2001, 'Part III: Systematic reviews of observational studies,' *In Systematic reviews in healthcare: meta-analysis in context*, 2nd ed. D. G. Altman, M. Egger, & G. D. Smith, eds., London: BMJ Books, pp. 209–282.

Eiser, C., Flynn, M., Green, E., Havermans, T., Kirby, R., Sandeman, D., & Tooke, J.E. 1992. Quality of life in young adults with type 1 diabetes in relation to demographic and disease variables. *Diabetic Medicine*, 9, (4) 375-378.

Elstad, E.A., Lutfey, K.E., Marceau, L.D., Campbell, S.M., von dem, K.O., & McKinlay, J.B. 2010. What do physicians gain (and lose) with experience? Qualitative results from a cross-national study of diabetes. *Social Science & Medicine*, 70, (11) 1728–1736.

Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P., Cording, E., Tomson, D., Dodd, C., Rollnick, S., Edwards, A., & Barry, M. 2012a. Shared Decision Making: A Model for Clinical Practice. *Journal of General Internal Medicine* [Epub ahead of print].

Elwyn, G., Lloyd, A., Joseph-Williams, N., Cording, E., Thomson, R., Durand, M.A., & Edwards, A. 2012b. Option Grids: Shared decision making made easier. *Patient Education and Counseling* [Epub ahead of print].

Estados Unidos Mexicanos. Constitucion Politica de los Estados Unidos Mexicanos. 1917. 17-4-2012.

Evans, J.M., Newton, R.W., Ruta, D.A., MacDonald, T.M., Stevenson, R.J., & Morris, A.D. 1999. Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. *British Medcial Journal*, 319, (7202) 83–86.

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.G. 2009. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behavior Research Methods*, 41, (4) 1149–1160.

Field, M.G. 1989. *Success and crisis in national health systems: a comparative approach* London, Routledge.

Flodgren, G., Eccles, M.P., Shepperd, S., Scott, A., Parmelli, E., & Beyer, F.R. 2011. An overview of reviews evaluating the effectiveness of financial incentives in changing healthcare professional behaviours and patient outcomes. Cochrane Database Systematic Reviews, (7) CD009255.

Fonseca, V.A. 2009. Defining and characterizing the progression of type 2 diabetes. *Diabetes Care*, 32 Suppl. 2, S151-S156.

Fortin, M., Hudon, C., Haggerty, J., Akker, M., & Almirall, J. 2010. Prevalence estimates of multimorbidity: a comparative study of two sources. *BMC Health Services Research*, 10, 111.

Foster, G., Taylor, S.J., Eldridge, S.E., Ramsay, J., & Griffiths, C.J. 2007. Self-management education programmes by lay leaders for people with chronic conditions. Cochrane Database Systematic Reviews, (4) CD005108.

Franciosi, M., Pellegrini, F., De, B.G., Belfiglio, M., Cavaliere, D., Di, N.B., Greenfield, S., Kaplan, S.H., Sacco, M., Tognoni, G., Valentini, M., & Nicolucci, A. 2001. The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients: an urgent need for better educational strategies. *Diabetes Care*, 24, (11) 1870–1877.

Franciosi, M., Pellegrini, F., De, B.G., Belfiglio, M., Di, N.B., Greenfield, S., Kaplan, S.H., Rossi, M.C., Sacco, M., Tognoni, G., Valentini, M., & Nicolucci, A. 2005. Self-monitoring of blood glucose in non-insulin-treated diabetic patients: a longitudinal evaluation of its impact on metabolic control. *Diabetic Medicine*, 22, (7) 900–906.

Francke, A.L., Smit, M.C., de Veer, A.J., & Mistiaen, P. 2008. Factors influencing the implementation of clinical guidelines for healthcare professionals: a systematic meta-review. *BMC Medical Informatics and Decision Making*, 8, 38.

Freeman, G.K., Horder, J.P., Howie, J.G., Hungin, A.P., Hill, A.P., Shah, N.C., & Wilson, A. 2002. Evolving general practice consultation in Britain: issues of length and context. *British Medical Journal*, 324, (7342) 880-882.

Freeman, G.K., Woloshynowych, M., Baker, R., Boulton, M., Guthrie, B., Car, J., Haggerty, J., & Tarrant, C. 2007, *Continuity of care 2006: what have we learned since 2000 and what are policy imperatives now? Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO)*.

Fried, L.P., Ferrucci, L., Darer, J., Williamson, J.D., & Anderson, G. 2004. Untangling the concepts of disability, frailty, and comorbidity: implications for improved targeting and care. *Journals of Gerontology. Series A, Biological Sciences and Medical Sciences*, 59, (3) 255–263.

Frier, B.M. 2009. Defining hypoglycaemia: what level has clinical relevance? *Diabetologia*, 52, (1) 31–34.

Fu, A.Z., Qiu, Y., Davies, M.J., Radican, L., & Engel, S.S. 2011. Treatment intensification in patients with type 2 diabetes who failed metformin monotherapy. *Diabetes, Obesity & Metabolism.*, 13, (8) 765–769.

Funnell, M.M., Brown, T.L., Childs, B.P., Haas, L.B., Hosey, G.M., Jensen, B., Maryniuk, M., Peyrot, M., Piette, J.D., Reader, D., Siminerio, L.M., Weinger, K., & Weiss, M.A. 2012. National standards for diabetes self-management education. *Diabetes Care*, 35 Suppl. 1, S101-S108.

Gafni, A., Walter, S.D., Birch, S., & Sendi, P. 2008. An opportunity cost approach to sample size calculation in cost-effectiveness analysis. *Health Economics*, 17, (1) 99–107.

Gallant, M.P. 2003. The influence of social support on chronic illness self-management: a review and directions for research. *Health Education & Behavior*, 30, (2) 170–195.

Garcia, A.A. 2008. Clinical and life quality differences between Mexican American diabetic patients at a free clinic and a hospital-affiliated clinic in Texas. *Public Health Nursing*, 25, (2) 149–158.

Garcia, A.A., Villagomez, E.T., Brown, S.A., Kouzekanani, K., & Hanis, C.L. 2001. The Starr County Diabetes Education Study: development of the Spanish-language diabetes knowledge questionnaire. *Diabetes Care*, 24, (1) 16–21.

Garduño-Espinosa, J., Tellez-Zenteno, J.F., & Hernandez-Ronquillo, L. 1998. [Frequency of depression in patients with diabetes mellitus type 2]. *Revista de Investigación Clínica.*, 50, (4) 287–291.

Garrett, N., Hageman, C.M., Sibley, S.D., Davern, M., Berger, M., Brunzell, C., Malecha, K., & Richards, S.W. 2005. The effectiveness of an interactive small group diabetes intervention in improving knowledge, feeling of control, and behavior. *Health Promotion Practice.*, 6, (3) 320–328.

Gary, T.L., Genkinger, J.M., Guallar, E., Peyrot, M., & Brancati, F.L. 2003. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educator*, 29, (3) 488–501.

Gellatly, J., Bower, P., Hennessy, S., Richards, D., Gilbody, S., & Lovell, K. 2007. What makes self-help interventions effective in the management of depressive symptoms? Meta-analysis and meta-regression. *Psychological Medicine*, 37, (9) 1217–1228.

Gerard, K. & Lattimer, V. 2005. Preferences of patients for emergency services available during usual GP surgery hours: a discrete choice experiment. *Family Practice*, 22, (1) 28-36.

Gerard, K., Salisbury, C., Street, D., Pope, C., & Baxter, H. 2008. Is fast access to general practice all that should matter? A discrete choice experiment of patients' preferences. *Journal of Health Services Research & Policy*, 13 Suppl 2, 3-10.

Gerring, J., Thacker, S.C., & Moreno, C. 2009. Are Parliamentary Systems Better? *Comparative Political Studies*, 42, (3) 327–359.

Gerstein, H.C., Miller, M.E., Byington, R.P., Goff, D.C., Jr., Bigger, J.T., Buse, J.B., Cushman, W.C., Genuth, S., Ismail-Beigi, F., Grimm, R.H., Jr., Probstfield, J.L., Simons-Morton, D.G., & Friedewald, W.T. 2008. Effects of intensive glucose lowering in type 2 diabetes. *New England Journal of Medicine*, 358, (24) 2545–2559.

Gilden, J.L., Casia, C., Hendryx, M., & Singh, S.P. 1990. Effects of self-monitoring of blood glucose on quality of life in elderly diabetic patients. *Journal of the American Geriatrics Society*, 38, (5) 511-515.

Gill, J.M., Mainous, A.G., III, Diamond, J.J., & Lenhard, M.J. 2003. Impact of provider continuity on quality of care for persons with diabetes mellitus. *Annals of Family Medicine*, 1, (3) 162–170.

Gillam, S.J., Siriwardena, A.N., & Steel, N. 2012. Pay-for-Performance in the United Kingdom: Impact of the Quality and Outcomes Framework - A Systematic Review. The Annals of Family Medicine, 10, (5) 461-468.

Glaesmer, H., Brahler, E., Martin, A., Mewes, R., & Rief, W. 2012. Gender Differences in Healthcare Utilization: The Mediating Effect of Utilization Propensity. *Journal of Applied Social Psychology*, 42, (5) 1266–1279.

Glasgow, R.E., Ruggiero, L., Eakin, E.G., Dryfoos, J., & Chobanian, L. 1997. Quality of life and associated characteristics in a large national sample of adults with diabetes. *Diabetes Care*, 20, (4) 562-567.

Glasziou, P. 2001. *Systematic reviews in healthcare: a practical guide* Cambridge, Cambridge University Press.

Goddijn, P.P., Bilo, H.J., Feskens, E.J., Groeniert, K.H., van der Zee, K.I., & Meyboom-de, J.B. 1999. Longitudinal study on glycaemic control and quality of life in patients with Type 2 diabetes mellitus referred for intensified control. *Diabetic Medicine*, 16, (1) 23-30.

Goldman, D.P. & Smith, J.P. 2002. Can patient self-management help explain the SES health gradient? *Proceedings of the National Academy of Sciences of the United States of America*, 99, (16) 10929–10934.

Gonzalez, J.S., Safren, S.A., Cagliero, E., Wexler, D.J., Delahanty, L., Wittenberg, E., Blais, M.A., Meigs, J.B., & Grant, R.W. 2007. Depression, self-care, and medication adherence in type 2 diabetes: relationships across the full range of symptom severity. *Diabetes Care*, 30, (9) 2222–2227.

Gonzalez, J.S., Safren, S.A., Delahanty, L.M., Cagliero, E., Wexler, D.J., Meigs, J.B., & Grant, R.W. 2008. Symptoms of depression prospectively predict poorer self-care in patients with Type 2 diabetes. *Diabetic medicine*, 25, (9) 1102–1107.

Gonzalez-Zuñiga, S. & Andrade-Islas, S. 2000. Educacion del paciente diabetico. Un problema ancestral. (Spanish). *Revista Medica del Instituto Mexicano del Seguro Social*, 38, (3) 187.

Grant, R., Adams, A.S., Trinacty, C.M., Zhang, F., Kleinman, K., Soumerai, S.B., Meigs, J.B., & Ross-Degnan, D. 2007. Relationship between patient medication adherence and subsequent clinical inertia in type 2 diabetes glycemic management. *Diabetes Care*, 30, (4) 807–812.

Grant, R.W., Pabon-Nau, L., Ross, K.M., Youatt, E.J., Pandiscio, J.C., & Park, E.R. 2011. Diabetes oral medication initiation and intensification: patient views compared with current treatment guidelines. *Diabetes Educator*, 37, (1) 78–84.

Graveling, A.J. & Frier, B.M. 2009. Hypoglycaemia: an overview. *Primary Care Diabetes*, 3, (3) 131–139.

Green, S.B. 1991. How Many Subjects Does It Take To Do A Regression Analysis. *Multivariate Behavioral Research*, 26, (3) 499–510.

Greenhalgh, T. 2007. *Primary healthcare: theory and practice* Oxford, Blackwell/BMJ Books.

Greenhalgh, T. & Heath, I. 2010, *Measuring quality in the therapeutic relationship*, Kings Fund, London.

Greenhalgh, T. & Heath, I. 2010a. Measuring quality in the therapeutic relationship--part 1: objective approaches. Quality & Safety in Health Care, 19, (6) 475-478.

Greenhalgh, T. & Heath, I. 2010b. Measuring quality in the therapeutic relationship--part 2: subjective approaches. Quality & Safety in Health Care, 19, (6) 479-483.

Greenhalgh, T. 2010. *How to read a paper: the basics of evidence-based medicine, 4th ed* Chichester, Wiley-Blackwell.

Grimes, D.A. & Schulz, K.F. 2002. Bias and causal associations in observational research. *Lancet*, 359, (9302) 248–252.

Grol, R., Wensing, M., Mainz, J., Jung, H.P., Ferreira, P., Hearnshaw, H., Hjortdahl, P., Olesen, F., Reis, S., Ribacke, M., & Szecsenyi, J. 2000. Patients in Europe evaluate general practice care: an international comparison. *British Journal of General Practice*, 50, (460) 882–887.

Grylls, W.K., McKenzie, J.E., Horwath, C.C., & Mann, J.I. 2003. Lifestyle factors associated with glycaemic control and body mass index in older adults with diabetes. *European Journal of Clinical Nutrition*, 57, (11) 1386–1393.

GSEDNu 1997. Diet and Day-to-Day Variability in a Sample of Spanish Adults with IDDM or NIDDM. *Hormone and Metabolic Research*, 29, (09) 450–453

Gulliford, M.C., Naithani, S., & Morgan, M. 2006. Measuring continuity of care in diabetes mellitus: an experience-based measure. *Annals of Family Medicine*, 4, (6) 548–555.

Gulliford, M.C., Naithani, S., & Morgan, M. 2007. Continuity of care and intermediate outcomes of type 2 diabetes mellitus. *Family Practice*, 24, (3) 245–251.

Guyatt, G.H. & Busse, J.W. 2006, 'The Philosophy of Evidence-Based Medicine Evidence-Based Endocrinology,' V.M. Montori, ed., Humana Press, pp. 25–33.

Guzman-Perez, M.A., Cruz-Cauich, A.J., Parra-Jimenez, J., & Manzano-Osorio, M. 2005. Glycaemic control, knowledge and self management from type 2 diabetic patients attending educational sessions. *Revista de Enfermeria del Instituto Mexicano del Seguro Social*, 13, (1) 9–13

Guzman-Saldana, R.M.E., Gomez-Peresmitre, G., Garcia-Meraz, M., & Castillo-Arreola, A. 2011. Factorial confirmatory analysis of the inventory of perceived self efficacy for weight control in Mexican population. *Psicologia Iberoamericana*, 19, (2) 78-88.

Haggerty, J.L., Reid, R.J., Freeman, G.K., Starfield, B.H., Adair, C.E., & McKendry, R. 2003. Continuity of care: a multidisciplinary review. *British Medical Journal*, 327, (7425) 1219–1221.

Hanninen, J., Takala, J., & Keinanen-Kiukaanniemi, S. 2001. Good continuity of care may improve quality of life in Type 2 diabetes. *Diabetes Research and Clinical Practice*, 51, (1) 21–27.

Hansen, L.J., Olivarius, N.F., Siersma, V., & Andersen, J.S. 2003. Doctors' characteristics do not predict long-term glycaemic control in type 2 diabetic patients. *British Journal of General Practice*, 53, (486) 47–49.

Harris, M.I. 2001. Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care*, 24, (6) 979–982.

Harrison, S. & Dowswell, G. 2002. Autonomy and bureaucratic accountability in primary care: what English general practitioners say. *Sociology of Health & Illness*, 24, (2) 208–226.

Hartz, A., Kent, S., James, P., Xu, Y., Kelly, M., & Daly, J. 2006. Factors that influence improvement for patients with poorly controlled type 2 diabetes. *Diabetes Research and Clinical Practice*, 74, (3) 227–232.

Haug, M.R., Akiyama, H., Tryban, G., Sonoda, K., & Wykle, M. 1991. Self care: Japan and the U.S. compared. *Social Science & Medicine*, 33, (9) 1011–1022.

Haynes, R.B., Devereaux, P.J., & Guyatt, G.H. 2002. Clinical expertise in the era of evidence-based medicine and patient choice. *Evidence Based Medicine*, 7, (2) 36–38.

Heath, I. 2008. Dare to use your own intelligence. *British Medical Journal*, 337, a1319.

Heath, I., Hippisley-Cox, J., & Smeeth, L. 2007. Measuring performance and missing the point? British Medical Journal, 335, (7629) 1075-1076.

Heath, I., Rubinstein, A., Stange, K.C., & van Driel, M.L. 2009. Quality in primary healthcare: a multidimensional approach to complexity. *British Medical Journal*, 338, b1242.

Heinrich, E., Schaper, N.C., & de Vries, N.K. 2010. Self-management interventions for type 2 diabetes: a systematic review. *European Diabetes Nursing*, 7, (2) 71–76.

Heisler, M., Piette, J.D., Spencer, M., Kieffer, E., & Vijan, S. 2005. The relationship between knowledge of recent HbA1c values and diabetes care understanding and self-management. *Diabetes Care*, 28, (4) 816–822.

Heisler, M., Smith, D.M., Hayward, R.A., Krein, S.L., & Kerr, E.A. 2003. How well do patients' assessments of their diabetes self-management correlate with actual glycemic control and receipt of recommended diabetes services? *Diabetes Care*, 26, (3) 738–743.

Hernan, M.A., Hernandez-Diaz, S., & Robins, J.M. 2004. A structural approach to selection bias. *Epidemiology*, 15, (5) 615–625.

Hernandez-Leyva, B.E., Garcia-Peña, C., Vazquez-Estupiñan, F., Villa-Contreras, S., & Guadarrama-Mijares, J. 2005, 'Self-help groups of obese or overweight, hypertensive, and diabetic patients', *In Family medicine at the dawn of the 21st century. Themes and arguments*, C. Garcia-Peña et al., eds, Mexico, D.F.: Instituto Mexicano del Seguro Social, pp. 211–238.

Hernandez-Romieu, A.C., Elnecave-Olaiz, A., Huerta-Uribe, N., & Reynoso-Noveron, N. 2011. [Analysis of population survey for determining the factors associated with the control diabetes mellitus in Mexico]. *Salud Publica de Mexico*, 53, (1) 34–39.

Higgins, J.P.T. & Green, S. Cochrane Handbook for systematic reviews of interventions Version 5.1.0 [updated March 2011]. http://www.cochrane-handbook.org/ 2011. The Cochrane Collaboration.

Hill-Briggs, F., Gary, T.L., Yeh, H.C., Batts-Turner, M., Powe, N.R., Saudek, C.D., & Brancati, F.L. 2006. Association of social problem solving with glycemic control in a sample of urban African Americans with type 2 diabetes. *Journal of Behavioral Medicine*, 29, (1) 69–78.

Hill-Briggs, F., Gemmell, L., Kulkarni, B., Klick, B., & Brancati, F.L. 2007. Associations of patient health-related problem solving with disease control, emergency department visits, and hospitalizations in HIV and diabetes clinic samples. *Journal of General Internal Medicine*, 22, (5) 649–654.

Holman, R.R., Paul, S.K., Bethel, M.A., Matthews, D.R., & Neil, H.A. 2008. 10-year follow-up of intensive glucose control in type 2 diabetes. *New England Journal of Medicine*, 359, (15) 1577-1589.

Horton, M., Rudick, R.A., Hara-Cleaver, C., & Marrie, R.A. 2010. Validation of a self-report comorbidity questionnaire for multiple sclerosis. *Neuroepidemiology*, 35, (2) 83–90.

Howick, J.H. 2011. *The Philosophy of Evidence-based Medicine* John Wiley & Sons.

Howie, J.G., Heaney, D., & Maxwell, M. 2004. Quality, core values and the general practice consultation: issues of definition, measurement and delivery. *Family Practice*, 21, (4) 458-468.

Huerta, J.M., Tormo, M.J., Egea-Caparros, J.M., Ortola-Devesa, J.B., & Navarro, C. 2009. Accuracy of self-reported diabetes, hypertension and hyperlipidemia in the adult Spanish population. DINO study findings. *Revista Española de Cardiología*, 62, (2) 143–152.

Huntley, A.L., Johnson, R., Purdy, S., Valderas, J.M., & Salisbury, C. 2012. Measures of multimorbidity and morbidity burden for use in primary care and community settings: a systematic review and guide. *Annals of Family Medicine*, 10, (2) 134–141.

Huppertz, E., Pieper, L., Klotsche, J., Stridde, E., Pittrow, D., Bohler, S., & Lehnert, H. 2009. Diabetes Mellitus in German Primary Care: quality of glycaemic control and subpopulations not well controlled – results of the DETECT study. *Experimental and Clinical Endocrinology & Diabetes*, 117, (1) 6–14.

IDF. HbA1c working group. http://www.idf.org/hba1c-working-group 2011a. 19-7-2012a.

IDF. Healthcare expenditures. http://www.idf.org/diabetesatlas/5e/healthcare-expenditures 2011b. 19-7-2012b.

IDF. Management of diabetes. http://www.idf.org/treatment-diabetes 2011c. 30-7-2012c.

IDF. The Global Burden. http://www.idf.org/diabetesatlas/5e/the-global-burden 2011d. 19-7-2012d.

IDF. Types of diabetes. http://www.idf.org/types-diabetes 2011e. 19-7-2012e.

IMSS. Diagnostico y Tratamiento de la Diabetes Mellitus Tipo 2. 2012. Mexico.

IMSS. Guia de practica clinica para el escrutinio, prevencion, diagnostico y tratamiento de la Diabetes y sus complicaciones en el Instituto Mexicano del Seguro Social. 2008. Mexico.

IMSS 2011, *Informe al ejecutivo federal y al congreso de la union sobre la situacion financiera y los riesgos del Instituto Mexicano del Seguro Social 2010–2011*, Instituto Mexicano del Seguro Social, Mexico, D.F.

IMSS. [X. Situacion de las instalaciones y equipo del instituto. En: Informe al Ejecutivo 2005-2006].
http://www.imss.gob.mx/instituto/informes/Pages/infoejecutivo2005_2006.aspx . 2006. 8-5-2013.

INEGI. Mexico en cifras. Poblacion derechohabiente a servicios de salud del IMSS 2010.
http://www2.inegi.org.mx/sistemas/mapatematicomexicocifras3d/default.aspx?e=0&mun=0&sec=M&ind=1004000002&ani=2010&src=0&i= 2010. 18-7-2012.

INEGI. Censo de poblacion y vivienda 2010: marco conceptual/Instituto Nacional Estadistica y Geografia. http://www.inegi.org.mx/sistemas/biblioteca/detalle.aspx?c=265&s=inegi&upc=702825002392&pf=Prod&f=0&cl=0&tg=0 2011. Mexico: INEGI. 20-6-2012.

INEGI 2012a, *Anuario estadistico de los Estados Unidos Mexicanos 2011*, Instituto Nacional de Estadistica y Geografia, Aguascalientes, Mexico.

INEGI. Mapoteca digital. http://solgeo.inegi.org.mx/mapoteca/frames.html 2012b. 11-7-2012b.

Institute of Medicine. Crossing the Quality Chasm: A new health system for the 21st century. http://www.nap.edu/openbook.php?isbn=0309072808 2001. Washington, D.C.: National Academy Press. 27-7-2011.

Institute of Medicine. Performance measurement: accelerating improvement. http://books.nap.edu/openbook.php?record_id=11517&page=R1 2006. Washington, D.C.: National Academy Press. 27-7-2011.

Inzucchi, S.E., Bergenstal, R.M., Buse, J.B., Diamant, M., Ferrannini, E., Nauck, M., Peters, A.L., Tsapas, A., Wender, R., & Matthews, D.R. 2012. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*, 35, (6) 1364-1379.

Jackson, G.L., Yano, E.M., Edelman, D., Krein, S.L., Ibrahim, M.A., Carey, T.S., Lee, S.Y., Hartmann, K.E., Dudley, T.K., & Weinberger, M. 2005. Veterans Affairs primary care organizational characteristics associated with better diabetes control. *American Journal of Managed Care*, 11, (4) 225–237.

Jacobson, A.M., de, G.M., & Samson, J.A. 1994. The evaluation of two measures of quality of life in patients with type I and type II diabetes. *Diabetes Care*, 17, (4) 267-274.

Jee, S.H. & Cabana, M.D. 2006. Indices for continuity of care: a systematic review of the literature. *Medical Care Research and Review*, 63, (2) 158–188.

Jerant, A.F., von Friederichs-Fitzwater, M.M., & Moore, M. 2005. Patients' perceived barriers to active self-management of chronic conditions. *Patient Education and Counseling.*, 57, (3) 300–307.

Johnson, P.E., Veazie, P.J., Kochevar, L., O'Connor, P.J., Potthoff, S.J., Verma, D., & Dutta, P. 2002. Understanding variation in chronic disease outcomes. *Health Care Management Science*, 5, (3) 175–189.

Joint Formulary Committee. British National Formulary (online ed.). http://www.bnf.org 2011. London: BMJ Group and Pharmaceutical Press. 19-7-2012.

Jurado, S., Villegas, M.E., Mendez, L., Rodriguez, F., Loperena, V., & Varela, R. 1998. La estandarizacion del Inventario de Depresion de Beck para los residentes de la ciudad de Mexico. *Salud Mental*, 21, (3) 26–31.

Kahn, K.L., Tisnado, D.M., Adams, J.L., Liu, H., Chen, W.P., Hu, F.A., Mangione, C.M., Hays, R.D., & Damberg, C.L. 2007. Does ambulatory process of care predict health-related quality of life outcomes for patients with chronic disease? *Health Services Research*, 42, (1 Pt 1) 63-83.

Karter, A.J., Ackerson, L.M., Darbinian, J.A., D'Agostino, R.B., Jr., Ferrara, A., Liu, J., & Selby, J.V. 2001. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry. *American Journal of Medicine*, 111, (1) 1–9.

Karter, A.J., Parker, M.M., Moffet, H.H., Spence, M.M., Chan, J., Ettner, S.L., & Selby, J.V. 2006. Longitudinal study of new and prevalent use of self-monitoring of blood glucose. *Diabetes Care*, 29, (8) 1757–1763.

Katch, H. & Mead, H. 2010. The role of self-efficacy in cardiovascular disease self-management: a review of effective programs. *Patient Intelligence*, 2, 33–44.

Katon, W., Russo, J., Lin, E.H., Heckbert, S.R., Karter, A.J., Williams, L.H., Ciechanowski, P., Ludman, E., & Von, K.M. 2009. Diabetes and poor disease control: is comorbid depression associated with poor medication adherence or lack of treatment intensification? *Psychosomatic Medicine*, 71, (9) 965–972.

Keinanen-Kiukaanniemi, S., Ohinmaa, A., Pajunpaa, H., & Koivukangas, P. 1996. Health related quality of life in diabetic patients measured by the Nottingham Health Profile. *Diabetic Medicine*, 13, (4) 382-388.

Kendall, E. & Rogers, A. 2007. Extinguishing the social?: state sponsored self-care policy and the Chronic Disease Self-management Programme. *Disability & Society*, 22, (2) 129-143.

Kennedy, A., Reeves, D., Bower, P., Lee, V., Middleton, E., Richardson, G., Gardner, C., Gately, C., & Rogers, A. 2007. The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial. *Journal of Epidemiology and Community Health*, 61, (3) 254–261.

Kenny, D.A. 1975. Cross-lagged panel correlation: A test for spuriousness. *Psychological Bulletin*, 82, (6) 887.

Kinmonth, A.L., Woodcock, A., Griffin, S., Spiegal, N., & Campbell, M.J. 1998. Randomised controlled trial of patient centred care of diabetes in general practice: impact on current wellbeing and future disease risk. The Diabetes Care From Diagnosis Research Team. *British Medical Journal*, 317, (7167) 1202-1208.

Kirk, J.K., Strachan, E., Martin, C.L., Davis, S.W., Peechara, M., & Lord, R. 2010. Patient characteristics and process of care measures as predictors of glycemic control. *Journal of Clinical Outcomes Mangement*, 17, (1) 27–30

Klassen, R.M. 2004. Optimism and realism: A review of self-efficacy from a cross-cultural perspective. *International Journal of Psychology*, 39, (3) 205-230.

Klein, C.E., Oboler, S.K., Prochazka, A., Oboler, S., Frank, M., Glugla, M., & Winters, S. 1993. Home blood glucose monitoring: effectiveness in a general population of patients who have non-insulin-dependent diabetes mellitus. *Journal of General Internal Medicine*, 8, (11) 597–601.

Knight, K., Badamgarav, E., Henning, J.M., Hasselblad, V., Gano, A.D., Jr., Ofman, J.J., & Weingarten, S.R. 2005. A systematic review of diabetes disease management programs. *American Journal of Managed Care*, 11, (4) 242–250.

Knight, K.M., Dornan, T., & Bundy, C. 2006. The diabetes educator: trying hard, but must concentrate more on behaviour. *Diabetic Medicine*, 23, (5) 485–501 available from: PM:16681557

Kristman, V., Manno, M., & Cote, P. 2004. Loss to follow-up in cohort studies: how much is too much? *European Journal of Epidemiology*, 19, (8) 751–760.

Lambert, H. 2006. Accounting for EBM: notions of evidence in medicine. *Social Science & Medicine*, 62, (11) 2633–2645.

Lara-Esqueda, A., Aroch-Calderon, A., Jimenez, R.A., Arceo-Guzman, M., & Velazquez-Monroy, O. 2004. [Mutual Help Groups: diabetes and hypertension control strategy]. *Archivos de Cardiología de México*, 74, (4) 330–336.

Leatherman, S. & Sutherland, K. The Quest for Quality: refining the NHS reforms. http://www.nuffieldtrust.org.uk/sites/files/nuffield/Quest_for_Quality_report-final-May2008.pdf 2008. The Nuffield Trust. London. 30-7-2012.

Legare, F., Ratte, S., Stacey, D., Kryworuchko, J., Gravel, K., Graham, I.D., & Turcotte, S. 2010. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews*, (5) CD006732.

Lehman, R. & Krumholz, H.M. 2009. Tight control of blood glucose in long standing type 2 diabetes. *British Medical Journal*, 338, b800.

Lenker, S.L., Lorig, K., & Gallagher, D. 1984. Reasons for the lack of association between changes in health behavior and improved health status: an exploratory study. *Patient Education and Counseling*, 6, (2) 69–72.

Lester, H.E., Hannon, K.L., & Campbell, S.M. 2011. Identifying unintended consequences of quality indicators: a qualitative study. BMJ Qual.Saf, 20, (12) 1057-1061.

Levin, L.S. 1976. The layperson as the primary healthcare practitioner. *Public Health Reports*, 91, (3) 206–210.

Levy, P.S. & Lemeshow, S. 2008. *Sampling of populations: methods and applications, 4th ed.* New Jersey, Wiley.

Lewin, S.A., Skea, Z.C., Entwistle, V., Zwarenstein, M., & Dick, J. 2001. Interventions for providers to promote a patient-centred approach in clinical consultations. *Cochrane Database of Systematic Reviews*, (4) CD003267.

Lo, R., Lo, B., Wells, E., Chard, M., & Hathaway, J. 1996. The development and evaluation of a computer-aided diabetes education program. *Australian Journal of Advanced Nursing*, 13, (4) 19-27.

Longo, M.F., Cohen, D.R., Hood, K., Edwards, A., Robling, M., Elwyn, G., & Russell, I.T. 2006. Involving patients in primary care consultations: assessing preferences using discrete choice experiments. *British Journal of General Practice*, 56, (522) 35-42.

Lohr, K.N. 2004. Rating the strength of scientific evidence: relevance for quality improvement programs. *International Journal for Quality in Health Care*, 16, (1) 9–18.

Londono, J.L. & Frenk, J. 1997. Structured pluralism: towards an innovative model for health system reform in Latin America. *Health Policy*, 41, (1) 1–36.

Lopez-Portillo, A., Bautista-Vidal, R.C., Rosales-Velasquez, O.F., Galicia-Herrera, L., & Escamilla, J.S. 2007. [Clinical control after diabetic and hypertension therapy group sessions]. *Revista Medica del Instituto Mexicano del Seguro Social*, 45, (1) 29–36.

Lopez-Torrecillas, F., Bulas, M., Leon-Arroyo, R., & Ramirez, I. 2005. Influencia del apoyo familiar en la autoeficacia de los drogodependientes. (Spanish). *Adicciones*, 17, (3) 241-249.

Lorig, K., Laurin, J., & Gines, G.E. 1984. Arthritis self-management. A five-year history of a patient education program. *Nursing Clinics of North America*, 19, (4) 637-645.

Lorig, K., Seleznick, M., Lubeck, D., Ung, E., Chastain, R.L., & Holman, H.R. 1989. The beneficial outcomes of the arthritis self-management course are not adequately explained by behavior change. *Arthritis and Rheumatism*, 32, (1) 91–95.

Lorig, K. 1996. *Outcome measures for health education and other health care interventions* Thousand Oaks : Sage Publications.

Lorig, K.R. & Holman, H. 2003. Self-management education: history, definition, outcomes, and mechanisms. *Annals of behavioral medicine*, 26, (1) 1–7.

Lorig, K., Ritter, P.L., Villa, F., & Piette, J.D. 2008. Spanish diabetes self-management with and without automated telephone reinforcement: two randomized trials. *Diabetes Care*, 31, (3) 408–414.

Lorig, K., Ritter, P.L., Villa, F.J., & Armas, J. 2009. Community-based peer-led diabetes self-management: a randomized trial. *Diabetes Educator*, 35, (4) 641–651.

Lorig, K., Ritter, P.L., Laurent, D.D., Plant, K., Green, M., Jernigan, V.B., & Case, S. 2010. Online diabetes self-management program: a randomized study. *Diabetes Care*, 33, (6) 1275–1281.

Lunsford, T.R. & Lunsford, B.R. 1995. The Research Sample, Part I: Sampling. *Journal of Prosthetics and Orthotics*, 7, (3).

Lustman, P.J., Clouse, R.E., Griffith, L.S., Carney, R.M., & Freedland, K.E. 1997. Screening for depression in diabetes using the Beck Depression Inventory. *Psychosomatic Medicine*, 59, (1) 24–31.

Lutfey, K.E., Campbell, S.M., Renfrew, M.R., Marceau, L.D., Roland, M., & McKinlay, J.B. 2008. How are patient characteristics relevant for physicians' clinical decision making in diabetes? An analysis of qualitative results from a cross-national factorial experiment. *Social Science & Medicine*, 67, (9) 1391–1399.

Macinko, J., Starfield, B., & Erinosho, T. 2009. The impact of primary healthcare on population health in low- and middle-income countries. *Journal of Ambulatory Care Management.*, 32, (2) 150–171.

Macinko, J., Starfield, B., & Shi, L. 2003. The contribution of primary care systems to health outcomes within Organization for Economic Cooperation and Development (OECD) countries, 1970–1998. *Health Services Research*, 38, (3) 831–865.

Macinko, J., Starfield, B., & Shi, L. 2007. Quantifying the health benefits of primary care physician supply in the United States. *International Journal of Health Services*, 37, (1) 111–126.

Magill, M.K. & Senf, J. 1987. A new method for measuring continuity of care in family practice residencies. *Journal of Family Practice*, 24, (2) 165–168.

Mainous, A.G., III, Koopman, R.J., Gill, J.M., Baker, R., & Pearson, W.S. 2004. Relationship between continuity of care and diabetes control: evidence from the Third National Health and Nutrition Examination Survey. *American Journal of Public Health*, 94, (1) 66–70.

Marchetti, P., Lupi, R., Del, G.S., Bugliani, M., D'Aleo, V., Occhipinti, M., Boggi, U., Marselli, L., & Masini, M. 2009. Goals of treatment for type 2 diabetes: beta-cell preservation for glycemic control. *Diabetes Care*, 32 Suppl. 2, S178-S183.

Marmot, M. 2005. Social determinants of health inequalities. *Lancet*, 365, (9464) 1099–1104.

Marshall, M., Lockwood, A., Bradley, C., Adams, C., Joy, C., & Fenton, M. 2000. Unpublished rating scales: a major source of bias in randomised controlled trials of treatments for schizophrenia. *British Journal of Psychiatry*, 176, 249–252.

Marshall, M.N., Roland, M.O., Campbell, S.M., Kirk, S., & Reeves, D. 2003. *Measuring general practice. A demostration project to develop and test a set of primary care clinical quality indicators* London, Nuffield Trust.

Martindale. The Complete Drug Reference. Sweetman, S.C. http://www.medicinescomplete.com/mc/martindale/current/ 2011. London: Pharmaceutical Press. 19-7-2012.

Martens, E.P., Pestman, W.R., de, B.A., Belitser, S.V., & Klungel, O.H. 2006. Instrumental variables: application and limitations. Epidemiology, 17, (3) 260-267.

Mason, B.J., Matsuyama, J.R., & Jue, S.G. 1995. Assessment of sulfonylurea adherence and metabolic control. *Diabetes Educator*, 21, (1) 52-57.

Mathew, R., Gucciardi, E., De, M.M., & Barata, P. 2012. Self-management experiences among men and women with type 2 diabetes mellitus: a qualitative analysis. *BMC Family Practice*, 13, 122.

Maxwell, R.J. 1992. Dimensions of quality revisited: from thought to action. *Quality in Health Care*, 1, (3) 171–177.

Mayou, R., Bryant, B., & Turner, R. 1990. Quality of life in non-insulin-dependent diabetes and a comparison with insulin-dependent diabetes. *Journal of Psychosomatic Research*, 34, (1) 1-11.

McCorkle, R., Ercolano, E., Lazenby, M., Schulman-Green, D., Schilling, L.S., Lorig, K., & Wagner, E.H. 2011. Self-management: Enabling and empowering patients living with cancer as a chronic illness. *CA: a Cancer Journal for Clinicians*, 61, (1) 50–62.

McDonald, R., Mead, N., Cheraghi-Sohi, S., Bower, P., Whalley, D., & Roland, M. 2007. Governing the ethical consumer: identity, choice and the primary care medical encounter. *Sociology of Health & Illness*, 29, (3) 430–456.

McGlynn, E.A., Asch, S.M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., & Kerr, E.A. 2003. The quality of health care delivered to adults in the United States. New England Journal of Medicine, 348, (26) 2635-2645.

McPherson, M.L., Smith, S.W., Powers, A., & Zuckerman, I.H. 2008. Association between diabetes patients' knowledge about medications and their blood glucose control. *Research in Social & administrative Pharmacy*, 4, (1) 37–45.

Mead, N. & Bower, P. 2000. Patient-centredness: a conceptual framework and review of the empirical literature. *Social Science & Medicine*, 51, (7) 1087–1110.

Mead, N. & Bower, P. 2002. Patient-centred consultations and outcomes in primary care: a review of the literature. *Patient Education and Counseling*, 48, (1) 51–61.

Mead, N., Bower, P., & Roland, M. 2008. The General Practice Assessment Questionnaire (GPAQ) – development and psychometric characteristics. *BMC Family Practice*, 9, 13.

Meads, G. 2006, 'Future Options for Family Medicine,' *In Primary Care in the Twenty-First Century: An international perspective*, G. Meads, ed., Oxford: Radcliffe, pp. 9–23.

Menard, J., Payette, H., Dubuc, N., Baillargeon, J.P., Maheux, P., & Ardilouze, J.L. 2007. Quality of life in type 2 diabetes patients under intensive multitherapy. *Diabetes & Metabolism*, 33, (1) 54-60.

Mercer, S.W. & Howie, J.G. 2006. CQI-2--a new measure of holistic interpersonal care in primary care consultations. *British Journal of General Practice*, 56, (525) 262-268.

Miles, A., Loughlin, M., & Polychronis, A. 2008. Evidence-based healthcare, clinical knowledge and the rise of personalised medicine. *Journal of Evaluation in Clinical Practice*, 14, (5) 621–649.

Mills, A.J. & Ranson, M. K. 2006, 'The design of health systems,' *In International public health: diseases, programs, systems, and policies*, M.H. Merson, R.E. Black, & A.J. Mills, eds., Sudbury, MA: Jones and Bartlett Publishers, pp. 513–552.

Mobashir, M., Varshney, D., & Gupta, S. 2005. Cardiovascular risk factors in type 2 diabetes mellitus. *Medicine Update*, 15,

Molinelli, A., Bonsignore, A., Rocca, G., & Ciliberti, R. 2009. Medical treatment and patient decisional power: the Italian state of the art. *Minerva Medica*, 100, (5) 429–434.

Montgomery, A.A., Peters, T.J., & Little, P. 2003. Design, analysis and presentation of factorial randomised controlled trials. *BMC Medical Research Methodology*, 3, 26.

Murata, G.H., Duckworth, W.C., Shah, J.H., Wendel, C.S., & Hoffman, R.M. 2004. Sources of glucose variability in insulin-treated type 2 diabetes: the Diabetes Outcomes in Veterans Study (DOVES). *Clinical Endocrinology (Oxford)*, 60, (4) 451–456.

Murata, G.H., Duckworth, W.C., Shah, J.H., Wendel, C.S., Mohler, M.J., & Hoffman, R.M. 2009. Blood glucose monitoring is associated with better glycemic control in type 2 diabetes: a database study. *Journal of General Internal Medicine*, 24, (1) 48–52.

Nagrebetsky, A., Griffin, S., Kinmonth, A.L., Sutton, S., Craven, A., & Farmer, A. 2012. Predictors of suboptimal glycaemic control in type 2 diabetes patients: the role of medication adherence and body mass index in the relationship between glycaemia and age. *Diabetes Research and Clinical Practice*, 96, (2) 119–128.

Naik, A.D., Palmer, N., Petersen, N.J., Street, R.L., Jr., Rao, R., Suarez-Almazor, M., & Haidet, P. 2011. Comparative effectiveness of goal setting in diabetes mellitus group clinics: randomized clinical trial. *Archives of Internal Medicine*, 171, (5) 453–459.

Nathan, D.M., Buse, J.B., Davidson, M.B., Ferrannini, E., Holman, R.R., Sherwin, R., & Zinman, B. 2009. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement

of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*, 32, (1) 193–203.

National Clinical Guideline Centre 2010. *Chronic heart failure: the management of chronic heart failure in adults in primary and secondary care* London, Royal College of Physicians.

National Collaborating Centre for Chronic Conditions 2008. *Type 2 diabetes: national clinical guideline for management in primary and secondary care (update)* London: Royal College of Physicians.

National Institute for Health and Clinical Excellence. Review of clinical guideline (CG66 and CG87 partial update) – Type 2 Diabetes: the management of type 2 diabetes. http://www.nice.org.uk/nicemedia/live/11983/56134/56134.pdf 2011. 19-7-2012.

Navarro Cardenas, J.M., Rodriguez, M.R., Munguia, M.C., & Hernandez Santiago, J.L. 2000. [Level of medical information on diabetes, attitude of patients towards their illness and its association with the level of blood sugar control]. *Atencion Primaria*, 26, (5) 283–286.

Ng, T.P., Goh, L.G., Tan, Y., Tan, E., Leong, H., Tay, E.G., & Thai, A.C. 2005. Ethnic differences in glycaemic control in adult Type 2 diabetic patients in primary care: a 3-year follow-up study. *Diabetic Medicine*, 22, (11) 1598–1604.

Nichols, G.A., Hillier, T.A., Javor, K., & Brown, J.B. 2000. Predictors of glycemic control in insulin-using adults with type 2 diabetes. *Diabetes Care*, 23, (3) 273–277.

Norris, S.L., Engelgau, M.M., & Narayan, K.M. 2001. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care*, 24, (3) 561–587.

Nunez, D.E., Keller, C., & Ananian, C.D. 2009. A review of the efficacy of the self-management model on health outcomes in community-residing older adults with arthritis. *Worldviews on Evidence-Based Nursing*, 6, (3) 130–148.

Nunnally, J.C. 1978. *Psychometric theory*, 2nd ed. New York; London: McGraw-Hill.

Nuovo, J., Balsbaugh, T., Barton, S., Fong, R., Fox-Garcia, J., Levich, B., & Fenton, J.J. 2007. Interventions to support diabetes self-management: the key role of the patient in diabetes care. *Current Diabetes Reviews*, 3, (4) 226–228.

O'Connor, A.M., Bennett, C.L., Stacey, D., Barry, M., Col, N.F., Eden, K.B., Entwistle, V.A., Fiset, V., Holmes-Rovner, M., Khangura, S., Llewellyn-Thomas, H., & Rovner, D. 2009. Decision aids for people facing health treatment or screening decisions. Cochrane Database Systematic Reviews, (3) CD001431.

O'Connor, P.J., Asche, S.E., Crain, A.L., Rush, W.A., Whitebird, R.R., Solberg, L.I., & Sperl-Hillen, J.M. 2004. Is patient readiness to change a predictor of improved glycemic control? *Diabetes Care*, 27, (10) 2325–2329.

Okura, Y., Urban, L.H., Mahoney, D.W., Jacobsen, S.J., & Rodeheffer, R.J. 2004. Agreement between self-report questionnaires and medical record data was substantial for diabetes, hypertension, myocardial infarction and stroke but not for heart failure. *Journal of Clinical Epidemiology*, 57, (10) 1096–1103.

Olaiz, G., Rojas, R., Barquera, S., Shamah, T., Aguilar, C., Cravioto, P., Lopez, M.P., Hernandez, M., Tapia, R., & Sepulveda, J. 2003. *Encuesta Nacional de Salud 2000. Tomo 2. La salud de los adultos* Cuernavaca, Morelos, Mexico, Instituto Nacional de Salud Publica.

Olaiz-Fernandez, G., Rivera-Dommarco, J., Shamah-Levy, T., Rojas, R., Villalpando-Hernandez, S., Hernandez-Avila, M., & Sepulveda-Amor, J. 2006. *Encuesta Nacional de Salud y Nutricion 2006* Cuernavaca, Mexico, Instituto Nacional de Salud Publica.

Orem, D.E. 1991. *Nursing: concepts of practice*, 4th ed. St. Louis, Missouri, USA, Mosby-Year Book.

Osuna, D., Barrera, M., Jr., Strycker, L.A., Toobert, D.J., Glasgow, R.E., Geno, C.R., Almeida, F., Perdomo, M., King, D., & Doty, A.T. 2011. Methods for the cultural adaptation of a diabetes lifestyle intervention for Latinas: an illustrative project. *Health Promotion Practice*, 12, (3) 341-348.

Otieno, C.F., Kariuki, M., & Ng'ang'a, L. 2003. Quality of glycaemic control in ambulatory diabetics at the out-patient clinic of Kenyatta National Hospital, Nairobi. *East African Medical Journal*, 80, (8) 406–410.

Overland, J., Yue, D.K., & Mira, M. 2001. Continuity of care in diabetes: to whom does it matter? *Diabetes Research and Clinical Practice*, 52, (1) 55–61.

Oxley, H., Colombo, F., Gil Lapetra, M.L., Braithwaite, V., Lopes, E., & Organisation for Economic Co-operation and Development. 2005. *Mexico* Paris: Organisation for Economic Co-operation and Development.

PAHO. Health in the Americas. Volume II – Countries. http://www.paho.org/hia/archivosvol2/paisesing/Mexico%20English.pdf 2007. 18-7-2012.

Parchman, M.L., Pugh, J.A., Noel, P.H., & Larme, A.C. 2002. Continuity of care, self-management behaviors, and glucose control in patients with type 2 diabetes. *Medical Care*, 40, (2) 137–144.

Paterick, T.J., Carson, G.V., Allen, M.C., & Paterick, T.E. 2008. Medical informed consent: general considerations for physicians. *Mayo Clinic Proceedings*, 83, (3) 313–319.

Pereira, A.G., Kleinman, K.P., & Pearson, S.D. 2003. Leaving the practice: effects of primary care physician departure on patient care. *Archives of Internal Medicine*, 163, (22) 2733–2736.

Persell, S.D., Keating, N.L., Landrum, M.B., Landon, B.E., Ayanian, J.Z., Borbas, C., & Guadagnoli, E. 2004. Relationship of diabetes-specific knowledge to self-management activities, ambulatory preventive care, and metabolic outcomes. *Preventive Medicine*, 39, (4) 746–752.

Petterson, T., Lee, P., Hollis, S., Young, B., Newton, P., & Dornan, T. 1998. Well-being and treatment satisfaction in older people with diabetes. *Diabetes Care*, 21, (6) 930-935.

Peyrot, M. & Rubin, R.R. 1997. Levels and risks of depression and anxiety symptomatology among diabetic adults. *Diabetes Care*, 20, (4) 585-590.

Piatt, G.A., Orchard, T.J., Emerson, S., Simmons, D., Songer, T.J., Brooks, M.M., Korytkowski, M., Siminerio, L.M., Ahmad, U., & Zgibor, J.C. 2006. Translating the chronic care model into the community: results from a randomized controlled trial of a multifaceted diabetes care intervention. *Diabetes Care*, 29, (4) 811–817.

Piette, J.D. & Kerr, E.A. 2006. The impact of comorbid chronic conditions on diabetes care. *Diabetes Care*, 29, (3) 725–731.

Pimouguet, C., Le, G.M., Thiebaut, R., Dartigues, J.F., & Helmer, C. 2011. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Canadian Medical Association Journal*, 183, (2) E115-E127.

Plochg, T. & Klazinga, N.S. 2002. Community-based integrated care: myth or must? *International Journal for Quality in Health Care*, 14, (2) 91–101.

Porta, M.S. 2008. *Dictionary of epidemiology, 5th ed* New York, Oxford University Press.

Porteous, T., Ryan, M., Bond, C.M., & Hannaford, P. 2006. Preferences for self-care or professional advice for minor illness: a discrete choice experiment. *British Journal of General Practice*, 56, (533) 911-917.

Prado-Aguilar, C.A. 2007. *[Indicadores de la calidad de atencion del medico familiar asociados a la severidad de la retinopatia en diabeticos tipo 2]*. PhD Universidad de Guadalajara-University of Washington.

Prado-Aguilar, C.A., Martinez, Y.V., Segovia-Bernal, Y., Reyes-Martinez, R., & rias-Ulloa, R. 2009. Performance of two questionnaires to measure treatment adherence in patients with Type-2 diabetes. *BMC Public Health*, 9, 38.

Presidencia de la Republica. Mexico. Regimen Politico. http://www.presidencia.gob.mx/mexico/ 2012. 12-7-2012.

Proctor, S. & Campbell, J. 1999. A developmental performance framework for primary care. *International Journal of Health Care Quality Qssurance Incorporating Leadership in Health Services*, 12, (6–7) 279–286.

Quilliam, B.J., Simeone, J.C., & Ozbay, A.B. 2011. Risk factors for hypoglycemia-related hospitalization in patients with type 2 diabetes: a nested case-control study. *Clinical Therapeutics*, 33, (11) 1781–1791.

Radhakrishnan, K. 2012. The efficacy of tailored interventions for self-management outcomes of type 2 diabetes, hypertension or heart disease: a systematic review. *Journal of Advanced Nursing*, 68, (3) 496–510.

Raleigh, V.S. & Foot, C. 2010. *Getting the measure of quality – opportunities and challenges* London, Kings Fund.

Ramlo-Halsted, B.A. & Edelman, S.V. 1999. The natural history of type 2 diabetes. Implications for clinical practice. *Primary Care*, 26, (4) 771–789.

Ramsay, J., Campbell, J.L., Schroter, S., Green, J., & Roland, M. 2000. The General Practice Assessment Survey (GPAS): tests of data quality and measurement properties. *Family Practice*, 17, (5) 372–379.

Raz, I., Soskolne, V., & Stein, P. 1988. Influence of small-group education sessions on glucose homeostasis in NIDDM. *Diabetes Care*, 11, (1) 67-71.

Reilly, S., Planner, C., Hann, M., Reeves, D., Nazareth, I., & Lester, H. 2012. The role of primary care in service provision for people with severe mental illness in the United kingdom. *Public Library of Science one*, 7, (5) e36468.

Renders, C.M., Valk, G.D., Griffin, S., Wagner, E.H., Eijk, J.T., & Assendelft, W.J. 2001. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database of Systematic Reviews,* (1) CD001481.

Resnick, H.E., Foster, G.L., Bardsley, J., & Ratner, R.E. 2006. Achievement of American Diabetes Association clinical practice recommendations among U.S. adults with diabetes, 1999–2002: the National Health and Nutrition Examination Survey. *Diabetes Care*, 29, (3) 531–537.

Richardson, G., Bojke, C., Kennedy, A., Reeves, D., Bower, P., Lee, V., Middleton, E., Gardner, C., Gately, C., & Rogers, A. 2009. What outcomes are important to patients with long term conditions? A discrete choice experiment. *Value in Health*, 12, (2) 331-339.

Rickheim, P.L., Weaver, T.W., Flader, J.L., & Kendall, D.M. 2002. Assessment of group versus individual diabetes education: a randomized study. *Diabetes Care*, 25, (2) 269-274.

Riddle, M., Umpierrez, G., DiGenio, A., Zhou, R., & Rosenstock, J. 2011. Contributions of basal and postprandial hyperglycemia over a wide range of A1C levels before and after treatment intensification in type 2 diabetes. *Diabetes Care*, 34, (12) 2508–2514.

Ritchie, C. 2007. Healthcare quality and multimorbidity: the jury is still out. *Medical Care*, 45, (6) 477–479.

Rodriguez-Moctezuma, J.R., Magdaleno-Tobias, M.E., Munguia-Miranda, C., Hernandez-Santiago, J.L., & Casas-de la Torre, E. 2003. Factores de los medicos familiares asociados al control glucemico de sus pacientes con diabetes mellitus. *Gaceta Medica de México*, 139, (2) 112–117

Rodriguez-Saldana, J., Morales de Teresa, M.A., Rosales-Campos, A.C., Clark, C.M., Mazze, R.S., & Strock, E. 2010. Effectiveness of staged diabetes management on the quality of diabetes care in Mexico. *Practical Diabetes International*, 27, (6) 242–247.

Roemer, M.I. 1993. National Health Systems Throughout the World. *American Behavioral Scientist*, 36, (6) 694–708.

Rogers, A., Vassilev, I., Sanders, C., Kirk, S., Chew-Graham, C., Kennedy, A., Protheroe, J., Bower, P., Blickem, C., Reeves, D., Kapadia, D., Brooks, H., Fullwood, C., & Richardson, G. 2011. Social networks, work and network-based resources for the management of long-term conditions: a framework and study protocol for developing self-care support. *Implementation Science*, 6, 56.

Rogosa, D. 1980. A critique of cross-lagged correlation. *Psychological Bulletin*, 88, (2) 245.

Rosland, A.M., Kieffer, E., Israel, B., Cofield, M., Palmisano, G., Sinco, B., Spencer, M., & Heisler, M. 2008. When is social support important? The association of family support and professional support with specific diabetes self-management behaviors. *Journal of General Internal Medicine*, 23, (12) 1992–1999.

Rothman, K.J., Greenland, S., & Lash, T.L. 2008. *Modern epidemiology, 3rd ed* Philadelphia, Lippincott Williams & Wilkins.

Rubin, G., Bate, A., George, A., Shackley, P., & Hall, N. 2006. Preferences for access to the GP: a discrete choice experiment. *British Journal of General Practice*, 56, (531) 743-748.

Ruiz Flores, L.G., Colin Piana, R.F., Corlay Noriega, I.S.-Y., Lara Munoz, Ma.d.C., & Duenas Tentori, H.J. 2007. Trastorno depresivo mayor en Mexico: la relacion entre la intensidad de la depresion, los sintomas fisicos dolorosos y la calidad de vida. (Spanish). *Salud Mental*, 30, (2) 25–32.

Ruiz-Hernandez, B., Reyes, Morales, H., Estrada-Obregon, C., Sanchez-Lopez, L.F., Pedrote-Navarro, B., Vargas-Alencaster, L.D., Michaus-Romero, F., Garcia-Peña, C., Perez-Cuevas, R. 2005, 'Family medicine at the Mexican Institute of Social Security: current strengths and weaknesses,' *In Family medicine at the dawn of the 21st century. Themes and arguments*, C. Garcia-Peña et al., eds., Mexico, D.F.: Instituto Mexicano del Seguro Social, pp. 37–48.

Ryan, M., Bate, A., Eastmond, C.J., & Ludbrook, A. 2001. Use of discrete choice experiments to elicit preferences. *Quality in Health Care*, 10 Suppl 1, i55-i60.

Ryan, A.M. & Doran, T. 2012. The effect of improving processes of care on patient outcomes: evidence from the United Kingdom's quality and outcomes framework. Medical Care, 50, (3) 191-199.

Ryan, M. & Farrar, S. 2000. Using conjoint analysis to elicit preferences for health care. *British Medical Journal*, 320, (7248) 1530-1533.

Safran, D.G., Kosinski, M., Tarlov, A.R., Rogers, W.H., Taira, D.H., Lieberman, N., & Ware, J.E. 1998. The Primary Care Assessment Survey: tests of data quality and measurement performance. *Medical Care*, 36, (5) 728–739.

Salcedo-Rocha, A.L., Garcia de Alba-Garcia, J., Frayre-Torres, M.J., & Lopez-Coutino, B. 2008. Genero y control de diabetes mellitus 2 en pacientes del primer nivel de atencion. (Spanish). *Revista Medica del Instituto Mexicano del Seguro Social*, 46, (1) 73–81.

Salomon, J.A., Carvalho, N., Gutierrez-Delgado, C., Orozco, R., Mancuso, A., Hogan, D.R., Lee, D., Murakami, Y., Sridharan, L., Medina-Mora, M.E., & Gonzalez-Pier, E. 2012. Intervention strategies to reduce the burden of non-communicable diseases in Mexico: cost effectiveness analysis. *British Medical Journal*, 344, e355.

Salter, K.L., Teasell, R.W., Foley, N.C., & Jutai, J.W. 2007. Outcome assessment in randomized controlled trials of stroke rehabilitation. *American Journal of Physical Medicine & Rehabilitation*, 86, (12) 1007–1012.

Samuels, D.S. 2007, 'Separation of powers,' *In The Oxford handbook of comparative politics*, S. Stokes & C. Boix, eds., Oxford, UK: Oxford University Press, pp. 703–726.

Sarkar, U., Karter, A.J., Liu, J.Y., Moffet, H.H., Adler, N.E., & Schillinger, D. 2010. Hypoglycemia is more common among type 2 diabetes patients with limited health literacy: the Diabetes Study of Northern California (DISTANCE). *Journal of General Internal Medicine*, 25, (9) 962–968.

Sarkisian, C.A., Brown, A.F., Norris, K.C., Wintz, R.L., & Mangione, C.M. 2003. A systematic review of diabetes self-care interventions for older, African American, or Latino adults. *Diabetes Educator*, 29, (3) 467–479.

Satterfield, J.M., Spring, B., Brownson, R.C., Mullen, E.J., Newhouse, R.P., Walker, B.B., & Whitlock, E.P. 2009. Toward a transdisciplinary model of evidence-based practice. *Milbank Quarterly*, 87, (2) 368–390.

Saultz, J.W. 2003. Defining and measuring interpersonal continuity of care. *Annals of Family Medicine*, 1, (3) 134–143.

Saultz, J.W. & Albedaiwi, W. 2004. Interpersonal continuity of care and patient satisfaction: a critical review. *Annals of Family Medicine*, 2, (5) 445–451.

Saultz, J.W. & Lochner, J. 2005. Interpersonal continuity of care and care outcomes: a critical review. *Annals of Family Medicine*, 3, (2) 159–166.

Schmidt, F.L. 1971. The Relative Efficiency of Regression and Simple Unit Predictor Weights in Applied Differential Psychology. *Educational and Psychological Measurement*, 31, (3) 699-714.

Schmittdiel, J.A., Uratsu, C.S., Karter, A.J., Heisler, M., Subramanian, U., Mangione, C.M., & Selby, J.V. 2008. Why don't diabetes patients achieve recommended risk factor targets? Poor adherence versus lack of treatment intensification. *Journal of General Internal Medicine*, 23, (5) 588–594.

Schutt, M., Kern, W., Krause, U., Busch, P., Dapp, A., Grziwotz, R., Mayer, I., Rosenbauer, J., Wagner, C., Zimmermann, A., Kerner, W., & Holl, R.W. 2006. Is the frequency of self-monitoring of blood glucose related to long-term metabolic control? Multicenter analysis including 24,500 patients from 191 centers in Germany and Austria. *Experimental and Clinical Endocrinology & Diabetes*, 114, (7) 384–388.

Scott, A., Sivey, P., Ait, O.D., Willenberg, L., Naccarella, L., Furler, J., & Young, D. 2011. The effect of financial incentives on the quality of health care provided by primary care physicians. Cochrane Database Systematic Reviews, (9) CD008451.

Scott, A., Watson, M.S., & Ross, S. 2003. Eliciting preferences of the community for out of hours care provided by general practitioners: a stated preference discrete choice experiment. *Social Science & Medicine*, 56, (4) 803-814.

Secretaria de Salud 2007, *Programa Nacional de Salud 2007–2012* Mexico.

Secretaria de Salud. Diagnostico, metas de control ambulatorio y referencia oportuna de la diabetes mellitus tipo 2 en el primer nivel de atencion. http://www.cenetec.salud.gob.mx/descargas/gpc/CatalogoMaestro/093_GPC_Diabmellitus2/SSA_093_08_EyR.pdf 2008. Mexico, Secretaria de Salud. 19-7-2012.

Secretaria de Salud. Sistema de Proteccion Social en Salud. Informe de resultados 2011. http://www.seguro-

popular.gob.mx/images/contenidos/Informes_Resultados/Informe_Resultados_2011.pdf 2012. 18-7-2012.

Selby, J.V., Uratsu, C.S., Fireman, B., Schmittdiel, J.A., Peng, T., Rodondi, N., Karter, A.J., & Kerr, E.A. 2009. Treatment intensification and risk factor control: toward more clinically relevant quality measures. *Medical Care*, 47, (4) 395–402.

Shalev, V., Chodick, G., Heymann, A.D., & Kokia, E. 2005. Gender differences in healthcare utilization and medical indicators among patients with diabetes. *Public Health*, 119, (1) 45–49.

Shamah Levy, T., Morales Ruan, C., Amaya Castellanos, C., Salazar Coronel, A., Jimenez Aguilar, A., & Mendez Gomez Humaran, I. 2012. Effectiveness of a diet and physical activity promotion strategy on the prevention of obesity in Mexican school children. *BMC Public Health*, 12, (1) 152.

Shaw, B.A., Gallant, M.P., Riley-Jacome, M., & Spokane, L.S. 2006. Assessing sources of support for diabetes self-care in urban and rural underserved communities. *Journal of Community Health*, 31, (5) 393–412.

Sherina, H.N., Teng, C.L., & Yasin, S. 2003. Continuity of care of diabetic patients in a family practice clinic: How important is it? *Asia Pacific Family Medicine*, 2, (1) 10–15.

Shi, L., Macinko, J., Starfield, B., Wulu, J., Regan, J., & Politzer, R. 2003a. The relationship between primary care, income inequality, and mortality in US States, 1980–1995. *Journal of the American Board of Family Medicine*, 16, (5) 412–422.

Shi, L., Macinko, J., Starfield, B., Xu, J., & Politzer, R. 2003b. Primary care, income inequality, and stroke mortality in the United States: a longitudinal analysis, 1985–1995. *Stroke*, 34, (8) 1958–1964.

Shi, L., Macinko, J., Starfield, B., Xu, J., Regan, J., Politzer, R., & Wulu, J. 2004. Primary care, infant mortality, and low birth weight in the states of the USA. *Journal of Epidemiology and Community Health*, 58, (5) 374–380.

Shi, L., Macinko, J., Starfield, B., Politzer, R., Wulu, J., & Xu, J. 2005a. Primary care, social inequalities and all-cause, heart disease and cancer mortality in US counties: a comparison between urban and non-urban areas. *Public Health*, 119, (8) 699–710.

Shi, L., Macinko, J., Starfield, B., Politzer, R., Wulu, J., & Xu, J. 2005b. Primary care, social inequalities, and all-cause, heart disease, and cancer mortality in US counties, 1990. *American Journal of Public Health*, 95, (4) 674–680.

Shi, L., Macinko, J., Starfield, B., Politzer, R., & Xu, J. 2005c. Primary care, race, and mortality in US states. *Social Science & Medicine*, 61, (1) 65–75.

Shojania, K.G., Ranji, S.R., McDonald, K.M., Grimshaw, J.M., Sundaram, V., Rushakoff, R.J., & Owens, D.K. 2006. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. *Journal of the American Medical Association*, 296, (4) 427–440.

Shrank, W.H., Asch, S.M., Adams, J., Setodji, C., Kerr, E.A., Keesey, J., Malik, S., & McGlynn, E.A. 2006. The quality of pharmacologic care for adults in the United States. *Medical Care*, 44, (10) 936-945.

Sidorenkov, G., Haaijer-Ruskamp, F.M., de, Z.D., Bilo, H., & Denig, P. 2011. Review: relation between quality-of-care indicators for diabetes and patient outcomes: a systematic literature review. *Medical Care Research and Review*, 68, (3) 263–289.

Singh, R. & Press, M. 2008. Can we predict future improvement in glycaemic control? *Diabetic Medicine*, 25, (2) 170–173.

Sixta, C.S. & Ostwald, S. 2008. Texas-Mexico border intervention by promotores for patients with type 2 diabetes. *Diabetes Educator*, 34, (2) 299–309.

Skyler, J.S., Bergenstal, R., Bonow, R.O., Buse, J., Deedwania, P., Gale, E.A., Howard, B.V., Kirkman, M.S., Kosiborod, M., Reaven, P., & Sherwin, R.S. 2009. Intensive glycemic control and the prevention of cardiovascular events: implications of the ACCORD, ADVANCE, and VA diabetes trials: a position statement of the American Diabetes Association and a scientific statement of the American College of Cardiology Foundation and the American Heart Association. *Diabetes Care*, 32, (1) 187–192.

Sousa, V.D., Zauszniewski, J.A., Musil, C.M., Price Lea, P.J., & Davis, S.A. 2005. Relationships among self-care agency, self-efficacy, self-care, and glycemic control. *Research and Theory for Nursing Practice*, 19, (3) 217–230.

SSA. Norma Oficial Mexicana NOM-015-SSA2–1994 Para la prevencion, tratamiento y control de la diabetes. 2000. 30-7-2012.

Stanford Patient Education Research Center. Diabetes Self-Efficacy Scale. Stanford Patient Education Research Center 2009. 8-6-2012.

Stanford Patient Education Research Center. Stanford Self-Management Programmes. http://patienteducation.stanford.edu/programs/ . 2013. 2-6-2013.

Starfield, B. 1980. Continuous confusion? *Am.J.Public Health*, 70, (2) 117–119.

Starfield, B., Shi, L., & Macinko, J. 2005. Contribution of primary care to health systems and health. *Milbank Quarterly*, 83, (3) 457–502.

Starfield, B. 1998. *Primary care: balancing health needs, services, and technology, Rev. ed* New York, Oxford University Press.

Stata Corporation. Stata Statistical Software. [10]. 2008. Texas, USA, StataCorp LP.

Steed, L., Cooke, D., & Newman, S. 2003. A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. *Patient Education and Counseling*, 51, (1) 5–15.

Steiger, J.H. 1980. Tests for comparing elements of a correlation matrix. *Psychological Bulletin*, 87, (2) 245–251

Stevens, G., Dias, R.H., Thomas, K.J., Rivera, J.A., Carvalho, N., Barquera, S., Hill, K., & Ezzati, M. 2008. Characterizing the epidemiological transition in Mexico: national and subnational burden of diseases, injuries, and risk factors. *Public Library of Science Medicine*, 5, (6) e125.

Stewart, M. 2001. Towards a global definition of patient centred care. *British Medical Journal*, 322, (7284) 444–445.

Stiggelbout, A.M., Van der Weijden, T., De Wit, M.P., Frosch, D., Legare, F., Montori, V.M., Trevena, L., & Elwyn, G. 2012. Shared decision making: really putting patients at the centre of healthcare. *British Medical Journal*, 344, e256.

Stokes, T., Tarrant, C., Mainous, A.G., III, Schers, H., Freeman, G., & Baker, R. 2005. Continuity of care: is the personal doctor still important? A survey of general practitioners and family physicians in England and Wales, the United States, and The Netherlands. *Annals of Family Medicine*, 3, (4) 353–359.

Street, R.L. Jr., Piziak, V.K., Carpentier, W.S., Herzog, J., Hejl, J., Skinner, G., & McLellan, L. 1993. Provider-patient communication and metabolic control. *Diabetes Care*, 16, (5) 714–721.

Streiner, D.L. & Norman, G.R. 1995. *Health measurement scales : a practical guide to their development and use* Oxford ; New York : Oxford University Press.

Suarez-Almazor, M.E., Belseck, E., Homik, J., Dorgan, M., & Ramos-Remus, C. 2000. Identifying clinical trials in the medical literature with electronic databases: MEDLINE alone is not enough. *Controlled Clinical Trials*, 21, (5) 476–487.

Summerton, N. 2011. *Primary care diagnostics – the patient-centred approach in the new commissioning environment*, Second ed. London, Radcliffe.

Tabachnick, B.G. & Fidell, L.S. 2001. *Using multivariate statistics, 4th ed.* Boston, Allyn and Bacon.

Tandon, A., Murray, C.J.L., Lauer, J, & Evans, D. Measuring overall health system performance for 191 countries. (GPE Discussion Paper No. 30), 1–23. 2000. Geneva, World Health Organization.

Tengblad, A., Grodzinsky, E., Lindstrom, K., Molstad, S., Borgquist, L., & Ostgren, C.J. 2007. Self-monitoring of blood glucose and glycaemic control in type 2 diabetes. *Scandinavian Journal of Primary Health Care*, 25, (3) 140–146.

The University of Manchester. EMBASE. Databases. http://www.library.manchester.ac.uk/searchresources/databases/e/dbname-69797-en.htm 2012a. The John Rylands University Library. 17-5-2012a.

The University of Manchester. Medline. Databases. http://www.library.manchester.ac.uk/searchresources/databases/m/dbname-70083-en.htm 2012b. The John Rylands University Library.

The University of Manchester. Ovid online. Databases. http://www.library.manchester.ac.uk/searchresources/databases/o/dbname-69692-en.htm 2012c. The John Rylands University Library. 17-5-2012c.

The World Bank Group. Country classification. http://econ.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20420458~isCURL:Y~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html . 2011. 17-4-2012

The World Bank Group. GNI per capita, Atlas method (current US$). http://data.worldbank.org/indicator/NY.GNP.PCAP.CD . 2012a. 6-9-2012a.

The World Bank Group. Life expectancy at birth, total (years). http://data.worldbank.org/indicator/SP.DYN.LE00.IN/countries?display=default . 2012b. 6-9-2012b.

The World Bank Group. Mexico. Data. http://data.worldbank.org/country/mexico . 2012b. 6-9-2012c.

Thorndike, R.L. & Hagen, E.P. 1977. *Measurement and evaluation in psychology and education*, 4th ed. New York; London: Wiley.

Tisnado, D.M., Adams, J.L., Liu, H., Damberg, C.L., Hu, A., Chen, W.P., & Kahn, K.L. 2007. Does concordance between data sources vary by medical organization type? *American Journal of Managed Care*, 13, (6 Part 1) 289–296.

Tobin, D.L., Reynolds, R.V.C., Holroyd, K.A., & Creer, T.L. 1986, 'Self-management and social learning theory,' *In Self-management of chronic disease: handbook of clinical interventions and research*, K.A. Holroyd & T.L. Creer, eds., Orlando: Academic Press, pp. 29–55.

Toobert, D.J., Hampson, S.E., & Glasgow, R.E. 2000. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*, 23, (7) 943–950.

Toobert, D., Strycker, L., Barrera, M., Osuna, D., King, D., & Glasgow, R. 2011. Outcomes from a Multiple Risk Factor Diabetes Self-Management Trial for Latinas: -¡Viva Bien! *Annals of Behavioral Medicine*, 41, (3) 310–323.

Toobert, D.J., Strycker, L.A., Glasgow, R.E., Barrera, J.M., & Angell, K. 2005. Effects of the mediterranean lifestyle program on multiple risk behaviors and psychosocial outcomes among women at risk for heart disease. Annals of Behavioral Medicine, 29, (2) 128-137.

Toth, E.L., Majumdar, S.R., Guirguis, L.M., Lewanczuk, R.Z., Lee, T.K., & Johnson, J.A. 2003. Compliance with clinical practice guidelines for type 2 diabetes in rural patients: treatment gaps and opportunities for improvement. *Pharmacotherapy*, 23, (5) 659–665.

Trivedi, A.N., Zaslavsky, A.M., Schneider, E.C., & Ayanian, J.Z. 2005. Trends in the quality of care and racial disparities in Medicare managed care. *New England Journal of Medicine*, 353, (7) 692–700.

Tseng, C.L., Brimacombe, M., Xie, M., Rajan, M., Wang, H., Kolassa, J., Crystal, S., Chen, T.C., Pogach, L., & Safford, M. 2005. Seasonal Patterns in Monthly Hemoglobin A1c Values. *American Journal of Epidemiology*, 161, (6) 565–574.

Tuerk, P.W., Mueller, M., & Egede, L.E. 2008. Estimating physician effects on glycemic control in the treatment of diabetes: methods, effects sizes, and implications for treatment policy. *Diabetes Care*, 31, (5) 869–873.

Turner, D., Tarrant, C., Windridge, K., Bryan, S., Boulton, M., Freeman, G., & Baker, R. 2007. Do patients value continuity of care in general practice? An investigation using stated preference discrete choice experiments. *Journal of Health Services Research and Policy*, 12, (3) 132–137.

Turner, R.C., Cull, C.A., Frighi, V., & Holman, R.R. 1999. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: progressive requirement for multiple therapies (UKPDS 49). UK Prospective Diabetes Study (UKPDS) Group. *Journal of the American Medical Association*, 281, (21) 2005-2012.

UKPDS 1998a. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group. *Lancet*, 352, (9131) 854–865.

UKPDS 1998b. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. *Lancet*, 352, (9131) 837–853.

UKPDS 1999. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). U.K. Prospective Diabetes Study Group. *Diabetes Care*, 22, (7) 1125-1136.

United Nations. Country profile. Mexico. http://data.un.org/CountryProfile.aspx?crName=Mexico 2012. 17-4-2012.

Valderas, J.M., Starfield, B., Sibbald, B., Salisbury, C., & Roland, M. 2009. Defining comorbidity: implications for understanding health and health services. *Ann.Fam.Med.*, 7, (4) 357–363.

van Bruggen, R., Gorter, K., Stolk, R., Klungel, O., & Rutten, G. 2009. Clinical inertia in general practice: widespread and related to the outcome of diabetes care. *Family Practice*, 26, (6) 428–436.

van der Does, F.E., de Neeling, J.N., Snoek, F.J., Grootenhuis, P.A., Kostense, P.J., Bouter, L.M., & Heine, R.J. 1998. Randomized study of two different target levels of glycemic control within the acceptable range in type 2 diabetes. Effects on well-being at 1 year. *Diabetes Care*, 21, (12) 2085-2093.

Vazquez-Martinez, J.L., Gomez-Dantes, H., & Fernandez-Canton, S. 2006. Diabetes mellitus en poblacion adulta del IMSS: Resultados de la Encuesta Nacional de Salud 2000. (Spanish). *Revista Medica del Instituto Mexicano del Seguro Social*, 44, (1) 13–26.

Velazquez-Abad, D.E. 2010. *[Validez de criterio concurrente de un cuestionario que valora la comunicacion en la relacion medico-paciente en Diabetes Mellitu tipo 2]*. Specialist in Family Medicine Universidad Autonoma de Aguascalientes.

Velazquez-Monroy, O., Lara-Esqueda, A., Martinez-Marroquin, M.Y., Tapia-Olarte, F., Jimenez, R.A., & Martinez-Abaunza, F. 2001. [Evaluation of self-help groups]. *Revista de Endocrinologia y Nutricion*, 9, (3) 126–132

Veldhuijzen, W., Elwyn, G., Ram, P.M., van-der-Weijden, T., van-Leeuwen, Y., & van-der-Vleuten, C.P. M. 2011, 'Beyond patient centeredness: the multitude of competing goals that doctors pursue in consultations,' *In Challenging the patient centred paradigm: designing feasible guidelines for doctor patient communication*, J.W. Veldhuijzen, ed., Maastricht: Maastricht University, pp. 115–132.

Venter, A., Maxwell, S.E., & Bolig, E. 2002. Power in randomized group comparisons: the value of adding a single intermediate time point to a traditional pretest-posttest design. *Psychological Methods*, 7, (2) 194-209.

Vincent, D., McEwen, M.M., & Pasvogel, A. 2008. The validity and reliability of a Spanish version of the summary of diabetes self-care activities questionnaire. *Nursing Research*, 57, (2) 101–106.

Vincent, D., Pasvogel, A., & Barrera, L. 2007. A feasibility study of a culturally tailored diabetes intervention for Mexican Americans. *Biological Research for Nursing*, 9, (2) 130–141.

Vlismas, K., Stavrinos, V., & Panagiotakos, D.B. 2009. Socio-economic status, dietary habits and health-related outcomes in various parts of the world: a review. *Central European Journal of Public Health*, 17, (2) 55-63.

von dem Knesebeck O., Gerstenberger, E., Link, C., Marceau, L., Roland, M., Campbell, S., Siegrist, J., de, C.W., & McKinlay, J. 2010. Differences in the diagnosis and management of type 2 diabetes in 3 countries (US, UK, and Germany): results from a factorial experiment. *Medical Care*, 48, (4) 321-326.

Wagner, E.H., Davis, C., Schaefer, J., Von, K.M., & Austin, B. 1999. A survey of leading chronic disease management programs: are they consistent with the literature? *Managed Care Quarterly*, 7, (3) 56–66.

Wagner, E.H., Glasgow, R.E., Davis, C., Bonomi, A.E., Provost, L., McCulloch, D., Carver, P., & Sixta, C. 2001. Quality improvement in chronic illness care: a collaborative approach. *Joint Commission Journal on Quality Improvement*, 27, (2) 63–80.

Watson, J.M. & Torgerson, D.J. 2006. Increasing recruitment to randomised trials: a review of randomised controlled trials. *BMC Medical Research Methodology*, 6, 34.

Wen, L.K., Shepherd, M.D., & Parchman, M.L. 2004. Family support, diet, and exercise among older Mexican Americans with type 2 diabetes. *Diabetes Educator*, 30, (6) 980–993.

WHO 2000, *Health Systems: Improving Performance* Geneva, Switzerland.

WHO 2007, *Everybody business: strengthening health systems to improve health outcomes: WHO's framework for action*, World Health Organization, Geneva, Switzerland.

WHO 2008. *The World Health Report 2008: primary healthcare: now more than ever* [Geneva, Switzerland], World Health Organization.

WHO. Cardiovascular diseases (CVDs). Fact sheet Nº 317. http://www.who.int/mediacentre/factsheets/fs317/en/index.html 2011a. 18-7-2012a.

WHO. Diabetes. http://www.who.int/mediacentre/factsheets/fs312/en/index.html [Fact sheet Nº312]. 2011b. 19-7-2012b.

WHO. Health systems, including primary healthcare. 19.4.2004 A57/14. World Health Organization. http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_14-en.pdf 2004. 30-7-2012.

WHO. International Classification of Diseases (ICD). http://www.who.int/classifications/icd/en/ 2012a. 4-7-2012a.

WHO. Social determinants of health. http://www.who.int/topics/social_determinants/en/ 2012b. 11-7-2012b.

World Health Organization. Health systems, including primary healthcare. 19.4.2004 A57/14. World Health Organization. http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_14-en.pdf 2004. 30-7-2012.

WHO & IDF 2006, *Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation*, WHO Press, Geneva, Switzerland.

WHO & SEARO 2009, *Self-care in the context of primary healthcare*, WHO, Bangkok, Thailand.

Wilson, W., Ary, D.V., Biglan, A., Glasgow, R.E., Toobert, D.J., & Campbell, D.R. 1986. Psychosocial predictors of self-care behaviors (compliance) and glycemic control in non-insulin-dependent diabetes mellitus. *Diabetes Care*, 9, (6) 614–622.

Wilson, A. & Childs, S. 2002. The relationship between consultation length, process and outcomes in general practice: a systematic review. *British Journal of General Practice*, 52, (485) 1012-1020.

WONCA Europe 2011, *The European definition of general practice/family medicine*, WHO Europe Office, Barcelona, Spain.

Wong, B.M., Garcia, Y., Barr, A., Glazier, R.H., & Abramson, B.L. 2008. Cardiovascular risk factor awareness in a disadvantaged inner-city population--implications for preventive strategies. *Canadian Journal Cardiology.*, 24, (9) 677-682.

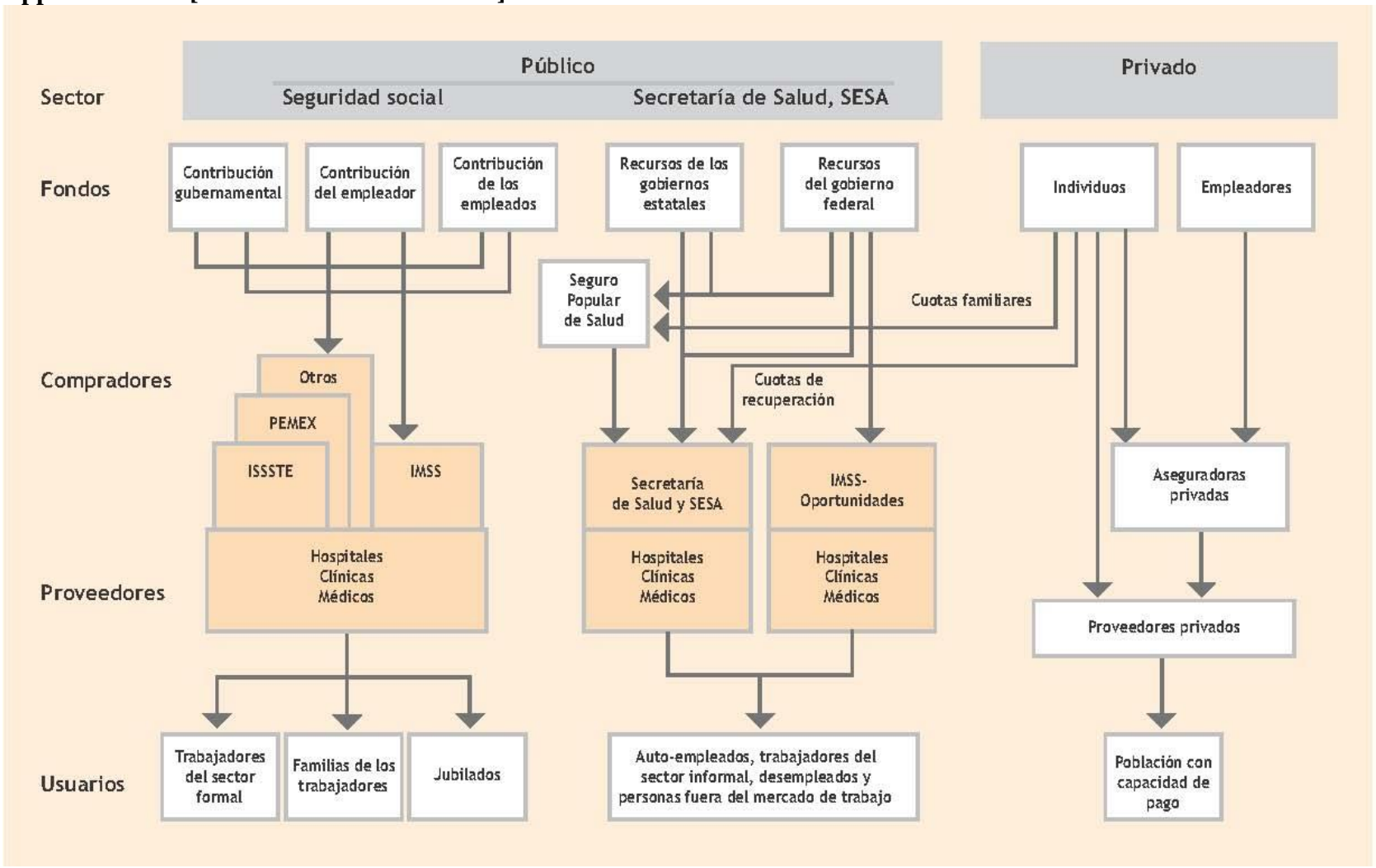
Woodward, M. 1999. *Epidemiology: study design and data analysis* Boca Raton, FL: Chapman & Hall/CRC Press.

Xu, J., Eilat-Adar, S., Loria, C.M., Howard, B.V., Fabsitz, R.R., Begum, M., Zephier, E.M., & Lee, E.T. 2007. Macronutrient intake and glycemic control in a population-based sample of American Indians with diabetes: the Strong Heart Study. *American Journal of Clinical Nutrition*, 86, (2) 480–487.

Xu, K.T. & Borders, T.F. 2003. Gender, health, and physician visits among adults in the United States. *American Journal of Public Health*, 93, (7) 1076–1079.

Ziemer, D.C., Miller, C.D., Rhee, M.K., Doyle, J.P., Watkins, C., Jr., Cook, C.B., Gallina, D.L., El-Kebbi, I.M., Barnes, C.S., Dunbar, V.G., Branch, W.T., Jr., & Phillips, L.S. 2005. Clinical inertia contributes to poor diabetes control in a primary care setting. *Diabetes Educator*, 31, (4) 564–571.

Appendix 3.1 [Sistema Nacional de Salud]



Appendix 8.1 Research project activities schedule

Activities	2009			2010									2010	2011			
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep Oct	Nov Feb	Mar May	Jun Jul	Ago Sep
Preparation of questionnaires, patient information sheets, and consent forms	❄	❄															
Training to interview and review		❄															
Piloting field work			❄														
Creation of database							❄										
Baseline data collection																	
Interviews with patients																	
Laboratory evaluations to collect glycaemic control, cholesterol, and triglycerides				❄	❄	❄	❄	❄									
Review of electronic medical records				❄	❄	❄	❄	❄									
Data entry								❄									
Data analysis									❄								
Baseline results														❄			

Activities	2009				2010									2010				
														2011				
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Nov	Mar	Jun	Ago
													Oct	Feb	May	Jul	Sep
Follow-up (6 months) data collection																		
Laboratory evaluations to collect glycaemic control, cholesterol, and triglycerides										❄	❄	❄	❄					
Data analysis														❄	❄			
Follow-up results														❄	❄			
Tables and graphs														❄	❄			
Report of results																❄	❄	
Discussion																❄	❄	
Conclusions																❄	❄	

❄ Activities in Mexico, ❄ Activities in Manchester

Appendix 8.2 Details of the practices involved in the research

Number of patients with diabetes per practice:

Practice Nº 1 = 6071 patients

Practice Nº 7 = 3510 patients

Practice Nº 8 = 7187 patients

Practice Nº 9 = 3386 patients

Practice Nº 10 = 6697 patients

Office consultations and general practitioners per practice:

Practice Nº 1 = 20 office consultations 40 general practitioners (20 GPs per session*)

Practice Nº 7 = 12 office consultations 24 general practitioners (12 per session)

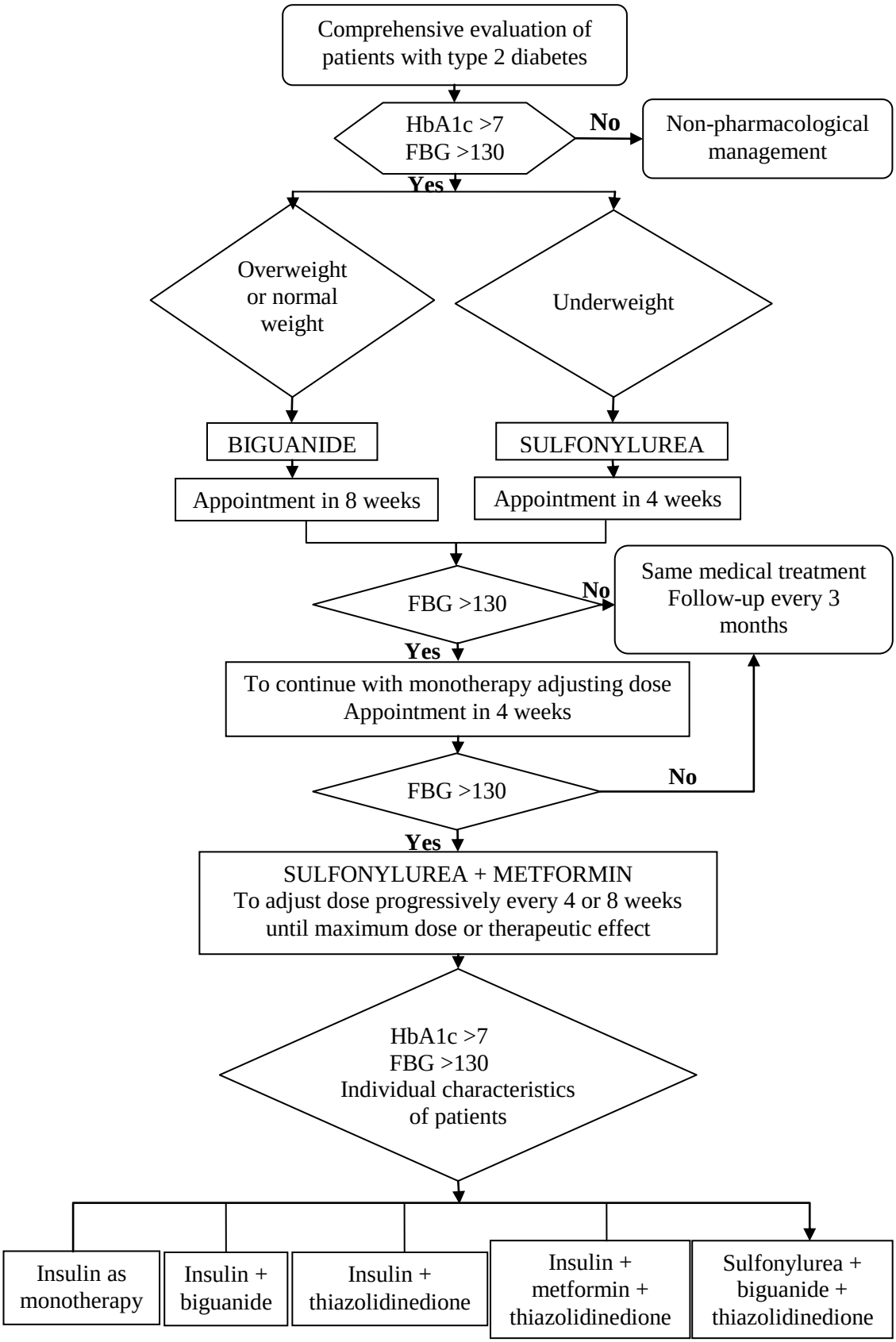
Practice Nº 8 = 20 office consultations 40 general practitioners (20 per session)

Practice Nº 9 = 10 office consultations 20 general practitioners (10 per session)

Practice Nº 10 = 19 office consultations 38 general practitioners (19 per session)

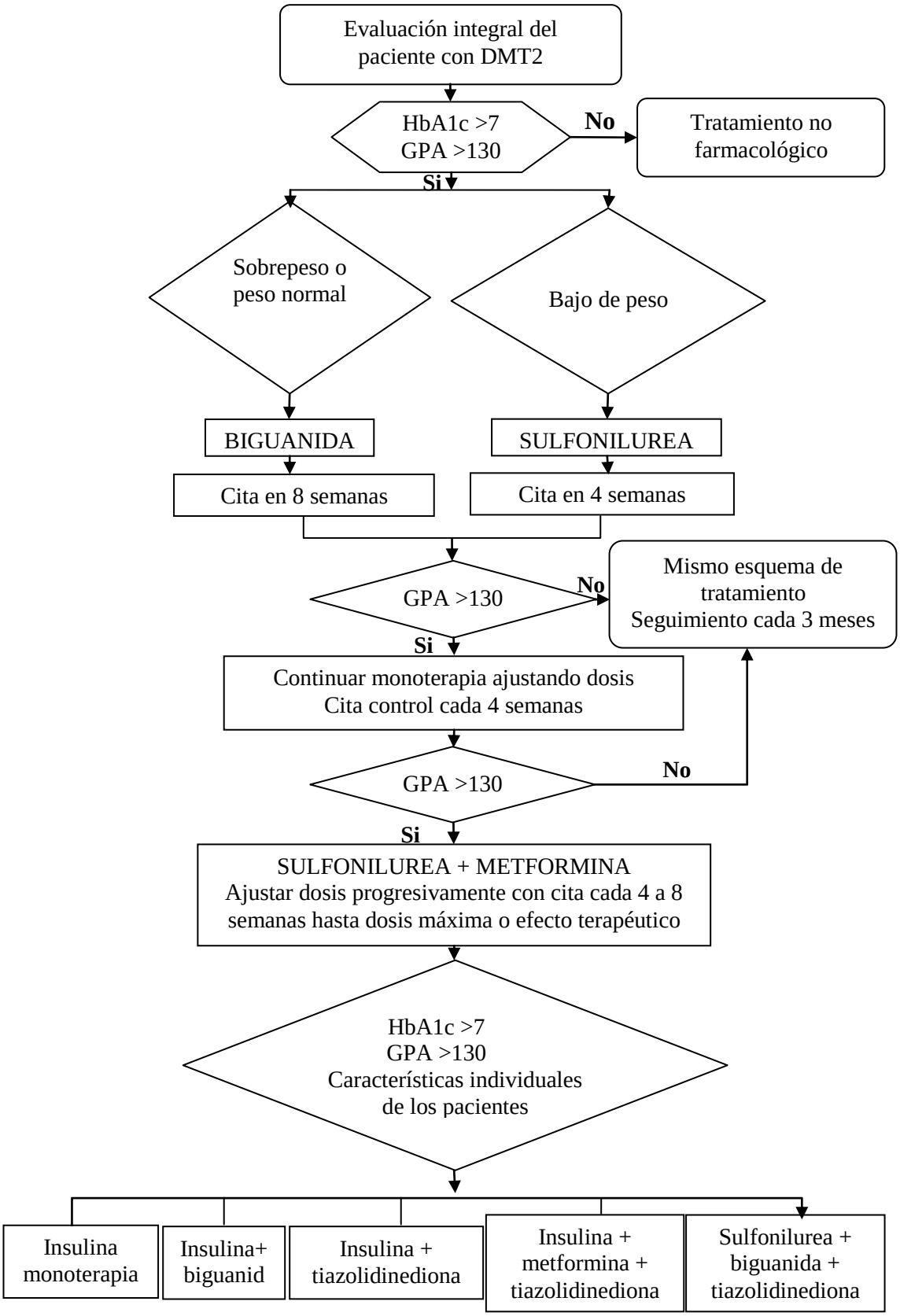
* Morning and afternoon session. Each session is 6.5 hours.

Appendix 8.3 Algorithm 2. Treatment of patients with type 2 diabetes in primary care with glucose-lowering agents (translated from IMSS 2008, p. 54)



HbA1c= glycosylated haemoglobin, FBG= fasting blood glucose, Sulfonylurea= glibenclamide, Biguanide= metformin, Thiazolidinediones= pioglitazone or rosiglitazone.

Appendix 8.3a Algorithm 2. Tratamiento con Antidiabeticos Orales en DM2 en Primer Nivel (IMSS 2008, p. 54) [Spanish original version]



HbA1c= fracción A1C de la hemoglobina glucosilada, GPA= glucosa plasmática en ayunas, Sulfonilureas= glibenclamida, Biguanida= metformina, Tiazolidinedionas= pioglitazona o rosiglitazona.

Appendix 8.4 Questionnaires and extraction forms – English and Spanish versions

MANCHESTER 1824

The University of Manchester

INSTITUTO MEXICANO DEL SEGURO SOCIAL

"THE INDIVIDUAL CONTRIBUTION AND RELATIVE IMPORTANCE OF SELF-MANAGEMENT AND QUALITY OF CARE ON GLYCAEMIC CONTROL IN MEXICAN PATIENTS WITH TYPE 2 DIABETES"

I. Demographic and clinical characteristics

Section I.1.- Personal information:

I.1.a.- Full name: _____
First name Surnames

I.1.b.- Date of recruitment: ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

I.1.c.- ID MISS number: ☐☐☐☐☐☐☐☐☐☐ _____

I.1.d.- Address: _____

I.1.e.- Telephone: _____ I.1.f.- Number of clinic ☐☐

I.1.g.- Office consultation: ☐☐ I.1.h.- Session:
1. *Morning* **2.** *Afternoon* ☐

Section I.2.- Demographic characteristics:

I.2.a.- Date of birth: ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

I.2.b.- Gender
1. *Male* **2.** *Female* ☐

I.2.c.- Level of education ☐
1. *No education (unable to read and write)*
2. *<6 years of education (able to read and write)*
3. *Primary school (6 years of education)*
4. *Secondary school (9 years of education)*
5. *Technician (12 years of education)*
6. *High school (12 years of education)*
7. *Undergraduate (17 years of education)*
8. *Postgraduate (>19 years of education)*

I.2.d.- Marital status
1. *Married* **2.** *Single* **3.** *Free union*
4. *Divorced* **5.** *Widow/widower* ☐

I.2.e.- Patient's occupation ☐☐
If patient is the head of family, you should register the code '99' in the item I.2.f

I.2.f.- Occupation of the head of family ☐☐

List of occupations for the items I.2.e and I.2.f
1. *Professional*
2. *Technician*
3. *Teacher*
4. *Artist, player*
5. *Manager in public sector*
6. *Business man/woman excluding agricultural sector*
7. *Manager, business man/woman in agricultural sector*
8. *Farm manager, foreperson*
9. *Agricultural laborer, farm worker, shepherd*
10. *Machine operator, agricultural sector*
11. *Factory foreperson*
12. *Factory worker*
13. *Factory assistant*
14. *Head of department, office worker, clerk*
15. *Merchant, sales person, shop assistant, sales agent*
16. *Hawker*
17. *Janitor*
18. *Maid*
19. *Driver*
20. *Armed forced/security worker*
21. *Artisan*
22. *Employee*
23. *House worker*
24. *Pensioner/retired*

25. *Student*
26. *No work activity*
99. *Not applicable*

Section I.3.- Clinical characteristics

I.3.a.- How long have you had diabetes? ☐☐ YEARS ☐☐ MONTHS

I.3.b.- How far is the clinic from your home? ☐.☐☐ KILOMETERS

I.3.c.- How much time do you spend going from your home to the clinic? ☐☐☐ MINUTES

I.3.d.- How do you travel to attend to your medical consultations? ☐

1. Car **2.** Bus **3.** Taxi **4.** Walking

I.3.e.- On average, how long does consultation with general practitioner last? ☐☐☐ MINUTES

I.3.f.- Do you know close people with diabetes? ☐

1. Yes **2.** Not

I.3.g.- If patient answer to the previous question is 'yes', you will ask her/him:
how many people with diabetes do you know?
The number of people with diabetes will be recorded in the boxes.
You then will ask to patient:
What kind of relationship do you have with these people? How many people are from every relationship? Who do you live with?

If patient answers to the previous question is 'no', you will record codes '9' or '99' in ALL the boxes (I.3.g.1.a to I.3.g.5.c) and continue with item I.4.

Kind of relationship		Number of close people		Live with patient		
I.3.g.1.a.-	☐	I.3.g.1.b.-	☐☐	I.3.g.1.c.-	**1.** Yes **2.** No	☐
I.3.g.2.a.-	☐	I.3.g.2.b.-	☐☐	I.3.g.2.c.-	**1.** Yes **2.** No	☐
I.3.g.3.a.-	☐	I.3.g.3.b.-	☐☐	I.3.g.3.c.-	**1.** Yes **2.** No	☐
I.3.g.4.a.-	☐	I.3.g.4.b.-	☐☐	I.3.g.4.c.-	**1.** Yes **2.** No	☐
I.3.g.5.a.-	☐	I.3.g.5.b.-	☐☐	I.3. g.5.c.-	**1.** Yes **2.** No	☐

Codes for kind of relationship
1. *Wife / husband / partner*
2. *Children*
3. *Parents*
4. *Sisters / brothers*
5. *Cousins / uncles / unties / / grandparents*
6. *Friends / neighbours / acquaintances*
7. *Others (specify)* _____

Section I.4.- Attendance to health education/self-management/self-care/self-help sessions

I.4.a.- Have you ever been in health education/self-management/self-care/self-help sessions?

If patient answers 'no', you will write code 9 or 99 in items I.4.b to I.4.f and continue with section I.5.

1. *Yes* **2.** *No* ☐

I.4.b.- Do you remember the kind of session that you attended?

1. *Yes* **2.** *No* **9.** *Not applicable* ☐

Kind of session: _____

I.4.c.- Did you attend this session in the Mexican Institute of Social Security (MISS) or in another institution?

1. *MISS* **2.** *Another institution* ☐

9. *Not applicable* *Institution* _____

I.4.d.- How many sessions did you attend? ☐☐

I.4.e.- When did you attend last session? ☐

1. *One month or less* **2.** *Two months* **3.** *Three months*
4. *Four months* **5.** *Five months* **6.** *Six months*
7. *Seven months or more* **9.** *No applicable*

I.4.f.- How useful were the sessions? ☐

1. *Very useful* **2.** *Useful* **3.** *Indifferent*
4. *Slightly useful* **5.** *Very useless* **9.** *No applicable*

Section I.5.- Comorbidity

Do you have any of the following conditions?

I.5.a.- Hypertension ☐
1. *Yes* **2.** *No*

I.5.b.- Eczema/dermatitis ☐
1. *Yes* **2.** *No*

I.5.c.- Angina ☐
1. *Yes* **2.** *No*

I.5.d.- Asthma ☐
1. *Yes* **2.** *No*

I.5.e.- Arthritis / rheumatism ☐
1. *Yes* **2.** *No*

I.5.f.- Depression ☐
1. *Yes* **2.** *No*

I.5.g.- Peptic/stomach ulcer or dyspepsia ☐
1. *Yes* **2.** *No*

I.5.h.- Gastritis ☐
1. *Yes* **2.** *No*

I.5.i.- Osteoporosis ☐
1. *Yes* **2.** *No*

I.5.j.- Heart failure ☐
1. *Yes* **2.** *No*

I.5.k.- Stroke ☐
1. *Yes* **2.** *No*

I.5.l.- Urinary incontinence ☐
1. *Yes* **2.** *No*

I.5.m.- Kidney failure ☐
1. *Yes* **2.** *No*

I.5.n.- Obesity ☐
1. *Yes* **2.** *No*

I.5.o.- Herpes ☐
1. *Yes* **2.** *No*

I.5.p.- Diabetes retinopathy ☐
1. *Yes* **2.** *No*

I.5.q.- Diabetes nephropathy ☐
1. *Yes* **2.** *No*

I.5.r.- Diabetes neuropathy ☐
1. *Yes* **2.** *No*

I.5.s.- Diabetic foot ☐
1. *Yes* **2.** *No*

II. Diabetes self-management

Section II.1.- Diabetes self-efficacy scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

II.1.a.- How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

II.1.b.- How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

II.1.c.- How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

II.1.d.- How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

II.1.e.- How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

II.1.f.- How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

not at all ┌┬┬┬┬┬┬┬┬┬┐ totally
confident 1 2 3 4 5 6 7 8 9 10 confident

II.1.g.- How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

not at all ┌┬┬┬┬┬┬┬┬┬┐ totally
confident 1 2 3 4 5 6 7 8 9 10 confident

II.1.h.- How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

not at all ┌┬┬┬┬┬┬┬┬┬┐ totally
confident 1 2 3 4 5 6 7 8 9 10 confident

Section II.2.- Medical Prescription Knowledge Questionnaire (MPKQ)

With the following three questions we wish to know how you take the medication prescribed by your general practitioner at the last medical visit.

Every item has codes to record patient's answer. Please, fill in the boxes with the corresponding code.

II.2.a.- What is the name of the diabetes medication prescribed by your general practitioner?

II.2.a.1.- Diabetes medications:

II.2.a.1.a.- Glibenclamide ☐

II.2.a.1.b.- Metformin ☐

II.2.a.1.c.- Acarbose ☐

II.2.a.1.d.- Pioglitazone ☐

II.2.a.1.e.- Rosiglitazone ☐

1. Patient names this medication

2. *Patient does not name this medication*

II.2.a.2.- Patient knows the name of the following medications:

II.2.a.2.a.- Glibenclamide ☐

II.2.a.2.b.- Metformin ☐

II.2.a.2.c.- Acarbose ☐

II.2.a.2.d.- Pioglitazone ☐

II.2.a.2.e.- Rosiglitazone ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.b.- How many times a day do you have to take your medication?

II.2.b.1.a.- Patient answers taking glibenclamide in the following frequency:

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

4. *Patient does not remember or does not know* **9.** *Not applicable*

II.2.b.2.a.- Patient knows prescribed frequency for glibenclamide

1. *Yes* **2.** *No* **9.** *Not applicable* ☐

II.2.b.1.b.- Patient answers taking metformin in the following frequency: ☐

1. Once a day (every 24 hours)

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

4. *Patient does not remember or does not know*

9. *Not applicable*

II.2.b.2.b.- Patient knows prescribed frequency for metformin

1. *Yes* **2.** *No* **9.** *Not applicable* ☐

II.2.b.1.c.- Patient answers taking acarbose in the following frequency: ☐

1. Once a day (every 24 hours)

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

4. *Patient does not remember or does not know*

9. *Not applicable*

II.2.b.2.c.- Patient knows prescribed frequency for acarbose

1. *Yes* **2.** *No* **9.** *Not applicable* ☐

II.2.b.1.d.- Patient answers taking pioglitazone in the following frequency: ☐

1. Once a day (every 24 hours)

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

4. *Patient does not remember or does not know*

9. *Not applicable*

II.2.b.2.d.- Patient knows prescribed frequency for pioglitazone

1. *Yes* **2.** *No* **9.** *Not applicable* ☐

II.2.b.1.e.- Patient answers taking rosiglitazone in the following frequency:

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

4. *Patient does not remember or does not know*

9. *Not applicable*

II.2.b.2.e.- Patient knows prescribed frequency for rosiglitazone ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.c.- How many tablets a day do you have to take each time?

II.2.c.1.a.- Patient answers taking glibenclamide in the following dose at each intake:

½ tablet at each intake (0.5) ☐.☐

1 tablet at each intake (1.0) ☐.☐

1 ½ tablets at each intake (1.5) ☐.☐

2 tablets at each intake (2.0)

5.0 *Patient does not remember or does not know*

9.9 *Not applicable*

II.2.c.2.a- Patient knows prescribed dose for glibenclamide ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.c.1.b.- Patient answers taking metformin in the following dose at each intake:

½ tablet at each intake (0.5) ☐.☐

1 tablet at each intake (1.0) ☐.☐

1 ½ tablets at each intake (1.5) ☐.☐

2 tablets at each intake (2.0)

5.0 *Patient does not remember or does not know*

9.9 *Not applicable*

II.2.c.2.b.- Patient knows prescribed dose for metformin ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.c.1.c.- Patient answers taking acarbose in the following dose at each intake:

½ tablet at each intake (0.5) ☐.☐
1 tablet at each intake (1.0) ☐.☐
1 ½ tablets at each intake (1.5) ☐.☐
2 tablets at each intake (2.0)
5.0 *Patient does not remember or does not know*
9.9 *Not applicable*

II.2.c.2.c.- Patient knows prescribed dose for acarbose ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.c.1.d.- Patient answers taking pioglitazone in the following dose at each intake:

½ tablet at each intake (0.5) ☐.☐
1 tablet at each intake (1.0) ☐.☐
1 ½ tablets at each intake (1.5) ☐.☐
2 tablets at each intake (2.0)
5.0 *Patient does not remember or does not know*
9.9 *Not applicable*

II.2.c.2.d.- Patient knows prescribed dose for pioglitazone ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.c.1.e.- Patient answers taking rosiglitazone in the following dose at each intake:

½ tablet at each intake (0.5) ☐.☐
1 tablet at each intake (1.0) ☐.☐
1 ½ tablets at each intake (1.5) ☐.☐
2 tablets at each intake (2.0)
5.0 *Patient does not remember or does not know*
9.9 *Not applicable*

II.2.c.2.e.- Patient knows prescribed dose for rosiglitazone ☐

1. *Yes* **2.** *No* **9.** *Not applicable*

II.2.d.- Has your general practitioner ever prescribed insulin treatment for you?

1. *Yes* **2.** *No* ☐

II.2.e.- Why are you not having insulin treatment?

Reason: _____ ☐☐

99. *Not applicable*

Section II.3.- Diabetes Knowledge Questionnaire (DKQ-24)

We would like to know your diabetes knowledge asking you the following 24 questions. Please, answer 'yes' when you think the statement is true. When you think the statement is false, please answer 'no'. When you are not sure if a statement is true or false, please answer 'I do not know'.

Item #	Questions	Yes	No	I do not know
II.3.a.-	Eating too much sugar and other sweet foods is a cause of diabetes.	0	1	0
II.3.b.-	The usual cause of diabetes is lack of effective insulin in the body.	1	0	0
II.3.c.-	Diabetes is caused by failure of the kidneys to keep sugar out of the urine.	0	1	0
II.3.d.-	Kidneys produce insulin	0	1	0
II.3.e.-	In untreated diabetes, the amount of sugar in the blood usually increases.	1	0	0
II.3.f.-	If I am diabetic, my children have a higher chance of being diabetic.	1	0	0
II.3.g.-	Diabetes can be cured.	0	1	0
II.3.h.-	A fasting blood sugar level of 210 is too high.	1	0	0
II.3.i.-	The best way to check my diabetes is by testing my urine.	0	1	0
II.3.j.-	Regular exercise will increase the need for insulin or other diabetic medication.	0	1	0
II.3.k.-	There are two main types of diabetes: Type 1 (insulin-dependent) and Type 2 (non-insulin-dependent).	1	0	0
II.3.l.-	An insulin reaction is caused by too much food.	0	1	0
II.3.m.	Medication is more important than diet and exercise to control my diabetes.	0	1	0
II.3.n.-	Diabetes often causes poor circulation.	1	0	0
II.3.o.-	Cuts and abrasions on diabetics heal more slowly.	1	0	0
II.3.p.-	Diabetics should take extra care when cutting their	1	0	0

Item #	Questions	Yes	No	I do not know
	toenails.			
II.3.q.-	A person with diabetes should cleanse a cut with iodine and alcohol.	0	1	0
II.3.r.-	The way I prepare my food is as important as the foods I eat.	1	0	0
II.3.s.-	Diabetes can damage my kidneys.	1	0	0
II.3.t.-	Diabetes can cause loss of feeling in my hands, fingers, and feet.	1	0	0
II.3.u.-	Shaking and sweating are signs of high blood sugar.	0	1	0
II.3.v.-	Frequent urination and thirst are signs of low blood sugar.	0	1	0
II.3.w.	Tight elastic hose or socks are not bad for diabetics.	0	1	0
II.3.x.-	A diabetic diet consists mostly of special foods.	0	1	0

Section II.4.- Summary of Diabetes Self-Care Activities (SDSCA)

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

II.4.a.- How many of the last SEVEN DAYS have you followed a healthful eating plan?

0 1 2 3 4 5 6 7 ☐

II.4.b.- On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7 ☐

II.4.c.- On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0 1 2 3 4 5 6 7 ☐

II.4.d.- On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7 ☐

II.4.e.- On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?

0 1 2 3 4 5 6 7 ☐

Exercise

II.4.f.- On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7 ☐

II.4.g.- On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other that what you do around the house or as part of your work?

0 1 2 3 4 5 6 7 ☐

Blood sugar testing

II.4.h.- On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7 ☐

II.4.i.- On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7 ☐

Foot care

II.4.j.- On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7 ☐

Smoking

II.4.k.- Have you smoked a cigarette – even one puff – during the last SEVEN DAYS?

0. No ☐

1. Yes

II.4.l.- If yes, how many cigarettes did you smoke on an average day?
Number of cigarettes: ☐☐

Medications

II.4.m.- On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?

0 1 2 3 4 5 6 7 ☐

III. Diabetes Quality of Care

Section III.1.- Continuity of care scale from the General Practice Assessment Questionnaire (GPAQ)

The next questions ask about your usual doctor. If you do not have a 'usual doctor', answer about the one doctor at your practice who you know the best. If you do not know any of the doctors, go straight to question III.2.a.

	Not at all	A bit	Some	Well	Very well	
III.1.a How well do you know your usual doctor?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
	None	One	Two	Three	Four	Five or more
III.1.b How many other doctors are there at your practice that you know as well?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

	Always	Almost always	A lot of the time	Some of the time	Almost never	Never
III.1.c In general, how often do you see your usual doctor?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

	Very poor	Poor	Fair	Good	Very good	Excellent
III.1.d How do you rate this?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Section III.2.-Patient – Doctor Communication Scale (PDCS)

The next 8 questions ask about how you are treated by your usual doctor during the consultation.

We would like you to think about **ALL** consultations that you have had with your usual doctor and answer how often you have experience every situation.

Item #. Questions	**Always**	**Almost always**	**Some times**	**Almost never**	**Never**
III.2.a.- The doctor greets you pleasantly	5	4	3	2	1
III.2.b.- The doctor pays attention while you explain him or her what is happening to you	5	4	3	2	1
III.2.c.- The doctor gives you an explanation of what is happening during the examination	5	4	3	2	1
III.2.d.- The doctor explains the reason why the treatment is the best for you	5	4	3	2	1
III.2.e.- The doctor gives importance to your questions	5	4	3	2	1
III.2.f.- The doctor gives you all the information that you expect	5	4	3	2	1
III.2.g.- Would you recommend this doctor to your friends?	5	4	3	2	1
III.2.h.- Would you like this doctor attended you next consultations?	5	4	3	2	1

Section III.3.-Patient Satisfaction with Diabetes Care questionnaire (PSDC)

The next 11 questions ask your **opinion** about things that can make you feel **satisfied** with the care given to you during the consultation.

Item #. Questions	**Strongly agree**	**Agree**	**Neither agree or disagree**	**Disagree**	**Strongly disagree**
III.3.a.- Did you expect that the sugar in your blood was not high when the doctor treated you?	5	4	3	2	1
III.3.b.- Did you expect that prescribed treatment was easy to comply?	5	4	3	2	1
III.3.c.- When the doctor started to treat you, did you expect that it did not take too much time following doctor's advice to control your diabetes?	5	4	3	2	1
III.3.d.- Did you expect to receive an appointment with the doctor in 2 days or before?	5	4	3	2	1
III.3.e.- Did you expect to receive an appointment with the doctor the same day you asked for it?	5	4	3	2	1
III.3.f.- Did you expect to be treated without making an appointment with the doctor?	5	4	3	2	1
III.3.g.- Did you expect that the doctor explained carefully what was the problem with your diabetes?	5	4	3	2	1
III.3.h.- Did you expect that the doctor explained carefully everything you have to do for your diabetes?	5	4	3	2	1
III.3.i.- Did you expect to talk with your doctor about all your health problems?	5	4	3	2	1
III.3.j.- Did you expect that the doctor respected your feelings?	5	4	3	2	1
III.3.k.- Did you expect that the doctor treated you respectfully?	5	4	3	2	1

The next 11 questions ask your **experience** about things that can make you feel **satisfied** with the care given to you during the consultation.

We would like you to think about **ALL** consultations that you have had with your usual doctor and that you answer how often you have experience every situation.

Item #. Questions	**Always**	**Almost always**	**Some times**	**Almost never**	**Never**
III.3.l.- How often is the sugar in your blood high in the laboratory evaluations?	1	2	3	4	5
III.3.m.- How often do you find difficulties to comply with the treatment that the doctor prescribes to you?	1	2	3	4	5
III.3.n.- How often does it take you too much time following doctor's advice to control your diabetes?	1	2	3	4	5
III.3.o.- How often do you receive an appointment with the doctor after 2 days you ask for it?	1	2	3	4	5
III.3.p.- How often do you receive an appointment with the doctor the same day you ask for it?	5	4	3	2	1
III.3.q.- How often are you treated by the doctor without making an appointment?	5	4	3	2	1
III.3.r.- How often does the doctor explain you carefully what is the problem with your diabetes?	5	4	3	2	1
III.3.s.- How often does the doctor explain you carefully everything you have to do for your diabetes?	5	4	3	2	1
III.3.t.- How often do you talk with your doctor about all your health problems?	5	4	3	2	1
III.3.u.- How often does the doctor not respect your feelings?	1	2	3	4	5
III.3.v.- How often do you feel that the doctor does not respect you?	1	2	3	4	5

IV.- Depression Beck Inventory

This questionnaire presents situations that you can feel, do, or think about in your everyday life. Please, pay attention in every situation and say what situation in every group best describes your feelings during the **LAST WEEK, <u>INCLUDING TODAY</u>**. Be sure to listen to all the situations in every group before you make a choice.

IV.a.- ☐

0. *I do not feel sad*

1. *I feel blue or sad*

2. *I am blue or sad all the time and I can't snap out of it*

3. *I am so sad or unhappy that I can't stand it*

IV.b.- ☐

0. *I am not particularly pessimistic or discouraged about the future*

1. *I feel discourage about the future*

2. *I feel I have nothing to look forward to*

3. *I feel that the future is hopeless and that things cannot improve*

IV.c.- ☐

0. *I do not feel like a failure*

1. *I feel I have failed more than the average person*

2. *As I look back on my life all I can see is a lot of failures*

3. *I feel I am a complete failure as a person (parent, husband, wife)*

IV.d.- ☐

0. *I am not particularly dissatisfied*

1. *I don't enjoy things the way I used to*

2. *I don't get satisfaction out of anything any more*

3. *I am dissatisfied with everything*

IV.e.-

0. *I don't feel particularly guilty*

1. *I feel bad or unworthy a good part of the time*

2. *I feel bad or unworthy practically all the time*

3. *I feel as though I am very bad or worthless*

IV.f.-

0. *I don't feel I am being punished*

1. *I feel I am being punished or will be punished*

2. *I feel I deserve to be punished*

3. *I want to be punished*

IV.g.-

0. *I don't feel disappointed in myself*

1. *I am disappointed in myself*

2. *I am disgusted with myself*

3. *I hate myself*

IV.h.-

0. *I don't feel I am any worse than anybody else*

1. *I am very critical of myself for my weaknesses or mistakes*

2. *I blame myself for everything that goes wrong*

3. *I feel I have many bad faults*

IV.i.-

0. *I don't have any thoughts of harming myself*

1. *I have thoughts of harming myself but I would not carry them out*

2. *I feel I would be better off dead*

3. *I would kill myself if I could*

IV.j.-

0. *I don't cry any more than usual*

1. *I cry more now than I used to*

2. *I cry all the time now. I can't stop it*

3. *I used to be able to cry but now I can't cry at all even though I want to*

IV.k.-

0. *I am not more irritated now than I ever am*

1. *I get annoyed or irritated more easily than I used to*

2. *I feel irritated all the time*

3. *I don't get irritated at all at the things that used to irritate me*

IV.l.-

0. *I have not lost interest in other people*

1. *I am less interested in other people now than I used to be*

2. *I have lost most of my interest in other people and I have little feeling for them*

3. *I have lost all my interest in other people and don't care about them at all*

IV.m.-

0. *I make decisions about as well as ever*

1. *I am less sure of myself now and try to put off making decisions*

2. *I can't make decisions any more without help*

3. *I can't make any decisions at all any more*

IV.n.-

0. *I don´t feel I look any worse than I used to*

1. *I am worried that I am looking old or unattractive*

2. *I feel that there are permanent changes in my appearance and they make me look unattractive*

3. *I feel that I am ugly or repulsive looking*

IV.o.-

0. *I can work about as well as before*

1. *It takes extra effort to get started at doing something*

2. *I have to push myself very hard to do anything*

3. *I can't do any work at all*

IV.p.-

0. *I can sleep as well as usual*

1. *I wake up more tired in the morning than I used to*

2. *I wake up 1-2 hours earlier than usual and find it hard to get back to sleep*

3. *I wake up early every day and can't get more than 5 hours sleep*

IV.q.-

0. *I don't get any more tired than usual*

1. *I get tired more easily than I used to*

2. *I get tired from doing anything*

3. *I get too tired to do anything*

IV.r.-

0. *My appetite is no worse than usual*

1. *My appetite is not as good as it used to be*

2. *My appetite is much worse now*

3. *I have no appetite at all any more*

IV.s.-

0. *I haven't lost much weight, if any, lately*

1. *I have lost more than 5 pounds*

2. *I have lost more than 10 pounds*

3. *I have lost more than 15 pounds*

IV.t.- ☐

0. *I am no more concerned about my health than usual*

1. *I am concerned about aches and pains or upset stomach or constipation or other unpleasant feelings in my body*

2. *I am so concerned with how I feel or what I feel that it's hard to think of much else*

3. *I am completely absorbed in what I feel*

IV.u.- ☐

0. *I have not noticed any recent change in my interest in sex*

1. *I am less interested in sex than I used to be*

2. *I am much less interested in sex now*

3. *I have lost interest in sex completely*

TOTAL ☐☐

V.- Data extraction from electronic medical record

Section V.1.- Blood pressure

V.1.a.- Systolic ☐☐☐ V.1.b.- Diastolic ☐☐☐

Section V.2.- Continuity of care

V.2.a.- Date of last consultation: ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

V.2.b.- Number of consultations in the previous six months ☐☐

V.2.c.- Number of consultations with same general practitioner in the previous six months ☐☐

Section V.3.- Treatment intensification

Date and recorded values in the electronic medical record: HbA1c, FBG, and BMI. *Take the most recent date and value during the previous 6 months.*
Note: it is possible that three values might not be in the last consultation, and then you can take them from different dates but within the previous two to six months.

V.3.a.- Date when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

V.3.b.- HbA1c level ☐☐.☐☐

V.3.c.- Date when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

V.3.d.- FBG level ☐☐☐.☐☐

V.3.e.- Date when BMI was recorded ☐☐ ☐☐ ☐☐☐☐
DAY *MONTH* *YEAR*

V.3.f.- BMI level ☐☐.☐☐

Section V.4.a.- Medical prescription

Take the most recent prescription during the previous 2 to 6 months. Use the same codes from section V.4. Medical prescription.

Name of medication		**Frequency of medication**	
Glibenclamide	☐	Glibenclamide	☐
Metformin	☐	Metformin	☐
Acarbose	☐	Acarbose	☐
Pioglitazone	☐	Pioglitazone	☐
Rosiglitazone	☐	Rosiglitazone	☐

Dosage of medication

Glibenclamide	☐☐.☐	☐☐.☐	☐☐.☐
Metformin	☐☐.☐	☐☐.☐	☐☐.☐
Acarbose	☐☐.☐	☐☐.☐	☐☐.☐
Pioglitazone	☐☐.☐	☐☐.☐	☐☐.☐
Rosiglitazone	☐☐.☐	☐☐.☐	☐☐.☐

Section V.4.- Medical prescription

Find GP's medical prescription for every patient in the electronic medical record. Write the code based on recorded medical prescription.

V.4.a.- Prescribed medications

V.4.a.1.-.Glibenclamide	☐
V.4.a.2.- Metformin	☐
V.4.a.3.- Acarbose	☐
V.4.a.4.- Pioglitazone	☐
V.4.a.5.- Rosiglitazone	☐

1. *Prescribed* **2.** *Not prescribed* **9.** *Not applicable*

V.4.b.- Frequency of medication per day

V.4.b.1.- Glibenclamide

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

9. Not applicable

V.4.b.2.- Metformin

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

9. Not applicable

V.4.b.3.- Acarbose

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

9. Not applicable

V.4.b.4.- Pioglitazone

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

9. Not applicable

V.4.b.5.- Rosiglitazone

1. Once a day (every 24 hours) ☐

2. Twice a day (every 12 hours)

3. Three times a day (every 8 hours)

9. Not applicable

V.4.c.- Dosage per medication

V.4.c.1.- Glibenclamide

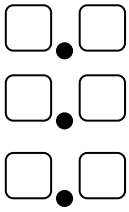
½ tablet at each intake (0.5)

1 tablet at each intake (1.0)

1 ½ tablets at each intake (1.5)

2 tablets at each intake (2.0)

9.9. *Not applicable*



V.4.c.2.- Metformine

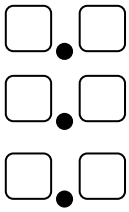
½ tablet at each intake (0.5)

1 tablet at each intake (1.0)

1 ½ tablets at each intake (1.5)

2 tablets at each intake (2.0)

9.9. *Not applicable*



V.4.c.3.- Acarbose

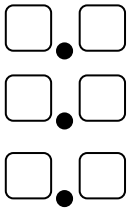
½ tablet at each intake (0.5)

1 tablet at each intake (1.0)

1 ½ tablets at each intake (1.5)

2 tablets at each intake (2.0)

9.9. *Not applicable*



V.4.c.4.- Pioglitazone

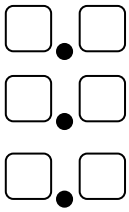
½ tablet at each intake (0.5)

1 tablet at each intake (1.0)

1 ½ tablets at each intake (1.5)

2 tablets at each intake (2.0)

9.9. *Not applicable*



V.4.c.5.- Rosiglitazone

½ tablet at each intake (0.5) ☐.☐

1 tablet at each intake (1.0) ☐.☐

1 ½ tablets at each intake (1.5) ☐.☐

2 tablets at each intake (2.0)

9.9. *Not applicable*

V.4.d.- Does the patient need treatment intensification? ☐

1. *Yes* **2.** *Not* **9.** *There is not information to measure treatment intensification (glycaemic control and/or medical prescription)*

V.4.e.- General practitioner intensifies medical treatment ☐

1. *Yes*

2. *Not*

3. *GP does not intensify because it is not necessary*

4. *GP intensifies when patient does not need intensification*

9. *There is not information to measure treatment intensification (glycaemic control and/or medical prescription)*

Section V.5.- HbA1c measurements

V.5.a.- Number of times that HbA1c was recorded in electronic medical record during previous 12 months ☐☐

Record dates of HbA1c, *starting with the most recent date*

V.5.a.1.- Date 1 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.2.- HbA1c level ☐☐.☐☐

V.5.a.3.- Date 2 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.4.- HbA1c level ☐☐.☐☐

V.5.a.5.- Date 3 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.6.- HbA1c level ☐☐.☐☐

V.5.a.7.- Date 4 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.8.- HbA1c level ☐☐.☐☐

V.5.a.9.- Date 5 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.10.- HbA1c level ☐☐.☐☐

V.5.a.11.- Date 6 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.12.- HbA1c level ☐☐.☐☐

V.5.a.13.- Date 7 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.14.- HbA1c level ☐☐.☐☐

V.5.a.15.- Date 8 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.16.- HbA1c level ☐☐.☐☐

V.5.a.17.- Date 9 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.18.- HbA1c level ☐☐.☐☐

V.5.a.19.- Date 10 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.20.- HbA1c level ☐☐.☐☐

V.5.a.21.- Date 11 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.22.- HbA1c level ☐☐.☐☐

V.5.a.23.- Date 12 when HbA1c was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.5.a.24.- HbA1c level ☐☐.☐☐

Section V.6.- FBG measurements

V.6.a.- Number of times that FBG was recorded in electronic medical record during previous 12 months ☐☐

Record dates of FBG, *starting with the most recent date*

V.6.a.1.- Date 1 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.2.- FBG level ☐☐.☐☐

V.6.a.3.- Date 2 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.4.- FBG level ☐☐.☐☐

V.6.a.5.- Date 3 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.6.- FBG level ☐☐.☐☐

V.6.a.7.- Date 4 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.8.- FBG level ☐☐.☐☐

V.6.a.9.- Date 5 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.10.- FBG level ☐☐.☐☐

V.6.a.11.- Date 6 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.12.- FBG level ☐☐.☐☐

V.6.a.13.- Date 7 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.14.- FBG level ☐☐.☐☐

V.6.a.15.- Date 8 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.16.- FBG level ☐☐.☐☐

V.6.a.17.- Date 9 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.18.- FBG level ☐☐.☐☐

V.6.a.19.- Date 10 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.20.- FBG level ☐☐.☐☐

V.6.a.21.- Date 11 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.22.- FBG level ☐☐.☐☐

V.6.a.23.- Date 12 when FBG was recorded ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

V.6.a.24.- FBG level ☐☐.☐☐

VI.- Information from laboratory evaluation-blood test

VI.a.- Date of blood test ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

VI.b.- HbA1c ☐☐.☐☐

VI.c.- FBG ☐☐☐.☐☐

VI.d.- Total cholesterol ☐☐☐.☐☐

VI.e.- Triglycerides ☐☐☐.☐☐

Month	Date of consultation	GP's ID	Glucose/ HbA1c	Month	Date of consultation	GP's ID	Glucose/ HbA1c

INSTITUTO MEXICANO DEL SEGURO SOCIAL

"CONTRIBUCION INDIVIDUAL E IMPORTANCIA RELATIVA DEL AUTO CUIDADO Y CALIDAD DE LA ATENCIÓN EN EL CONTROL GLUCÉMICO DE PACIENTES MEXICANOS CON DIABETES TIPO 2"

I. Características sociodemográficas y clínicas

Sección I.1.- Ficha de identificación:

I.1.a.- Nombre: _____
Nombre (s) Apellido paterno Apellido materno

I.1.b.- Fecha de aplicación: ☐☐ ☐☐ ☐☐☐☐
DIA *MES* *AÑO*

I.1.c.- Número de afiliación: ☐☐☐☐☐☐☐☐☐☐ _____
Calidad

I.1.d.- Domicilio: _____
Calle y numero colonia ciudad apartado postal

I.1.e.- Teléfono: _____ I.1.f.- UMF de adscripción ☐☐

I.1.g.- Número de consultorio: ☐☐ I.1.h.- Turno:
1. *Matutino* **2.** *Vespertino* ☐

Sección I.2.- Datos sociodemográficos:

I.2.a.- Fecha de nacimiento: ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

I.2.b.- Género
1. *Masculino* **2.** *Femenino* ☐

I.2.c.- Nivel de estudios ☐
1. *Analfabeta (no sabe leer ni escribir)*
2. *Alfabeta sin escolaridad (sabe leer y escribir)*
3. *Primaria (terminó primaria y cuenta con certificado)*
4. *Secundaria (terminó secundaria y cuenta con certificado)*
5. *Técnico profesional (terminó carrera técnica y cuenta con certificado)*
6. *Preparatoria (terminó preparatoria y cuenta con certificado)*
7. *Profesional (terminó carrera universitaria y cuenta con certificado)*
8. *Otro (terminó algún posgrado y cuenta con certificado)*

I.2.d.- Estado civil actual ☐
1. *Casado (a)* **2.** *Soltero (a)* **3.** *Unión libre*
4. *Divorciado (a)* **5.** *Viudo (a)*

I.2.e.- Ocupación actual del paciente ☐☐
Si el paciente es el jefe de familia,
se registrara el código 99 en el ítem I.2.f

I.2.f.- Ocupación actual del jefe de familia ☐☐

Listado de codificación para los ítems I.2.e y I.2.f
1. *Profesional (medico, licenciado, arquitecto, etc.)*
2. *Técnicos y personal especializado*
3. *Trabajadores de la enseñanza*
4. *Trabajadores del arte, espectáculos, deporte (artistas, futbolistas, etc.)*
5. *Funcionarios supervisores y de categoría directiva de la administración pública*
6. *Funcionarios superiores, administradores y propietarios del sector privado, excepto agropecuario.*
7. *Administradores, gerentes y propietarios del sector agropecuario*
8. *Inspectores, capataces y mayorales en el proceso de producción agropecuaria*
9. *Trabajadores directos en la producción agropecuaria (pastor, peón del campo etc.)*
10. *Operadores de máquina y personal de apoyo en procesos de producción agropecuaria (tractoristas, etc)*
11. *Supervisores, capataces y personal de control en el proceso de producción industrial*
12. *Trabajadores directos en la producción industrial (obrero, torno, etc.)*
13. *Ayudante, auxiliares y peones en el proceso industrial (obreros, ayudantes en general)*
14. *Jefe de departamento, oficinista y trabajador intermedio e inferior (secretaria, analista etc.)*
15. *Comerciantes, vendedores, dependientes y agente de ventas*
16. *Vendedor sin establecimiento fijo (todos los ambulantes)*
17. *Trabajadores en servicios públicos y personales, excepto domésticos (intendentes, etc.)*
18. *Trabajador en servicios domésticos*

19. *Operador y conductor de equipo de transporte excepto chóferes particulares*
20. *Trabajador de las fuerzas armadas y de servicios de protección y vigilancia (cabo, policía bombero)*
21. *Trabajos artesanales*
22. *Empleados*
23. *Hogar*
24. *Jubilados / pensionados*
25. *Estudiante.*
26. *No realiza actividad laboral*
99. *No aplica*

Sección I.3.- Características de la diabetes y su atención

I.3.a.- ¿Cuánto tiempo tiene de padecer diabetes? (años y meses) ☐☐☐☐
AÑOS MESES

I.3.b.- ¿Que tan lejos está la unidad de medicina familiar de su casa? (kilómetros) ☐☐.☐

I.3.c.- ¿Cuánto tiempo se tarda en llegar a la unidad de medicina familiar? (minutos) ☐☐

I.3.d.- ¿Qué medio de transporte utiliza para asistir a sus consultas en la unidad de medicina familiar? ☐
1. Automóvil propio **2.** Camión
3. Taxi **4.** Ninguno (caminando)

I.3.e.- Regularmente, ¿cuántos minutos dura su consulta con el médico familiar? (minutos) ☐☐

I.3.f.- ¿Conoce personas cercanas a usted que tengan diabetes? ☐
1. Si **2.** No

I.3.g.- Si la respuesta a la pregunta I.3. f. es 'Si', se le pregunta al paciente ¿Cuántas personas conoce que tengan diabetes? Y el número de personas se registra en los espacios correspondientes al ítem I.3.g. Además se realizaran las siguientes preguntas y se le registraran en las columnas correspondientes:

¿Qué tipo de parentesco/amistad tiene con esas personas? ¿Cuántas son de cada tipo de parentesco/amistad? y ¿Quiénes viven con usted?
Si la respuesta a la pregunta I.3. f. es 'No', pasar a la pregunta I.4.a.- y escribir el código 9 y 99 en todas las casillas correspondientes al ítem I.3.g.

Parentesco/amistad		Numero de personas		Viven con usted			
I.3.g.1.a.-	☐	I.3.g.1.b.-	☐☐	I.3.g.1.c.-	**1.** Si	**2.** No	☐
I.3.g.2.a.-	☐	I.3.g.2.b.-	☐☐	I.3.g.2.c.-	**1.** Si	**2.** No	☐
I.3.g.3.a.-	☐	I.3.g.3.b.-	☐☐	I.3.g.3.c.-	**1.** Si	**2.** No	☐
I.3.g.4.a.-	☐	I.3.g.4.b.-	☐☐	I.3.g.4.c.-	**1.** Si	**2.** No	☐
I.3.g.5.a.-	☐	I.3.g.5.b.-	☐☐	I.3. g.5.c.-	**1.** Si	**2.** No	☐

Códigos para parentesco/amistad
1. *Esposa (o)*
2. *Hijos (as)*
3. *Padres*
4. *Hermanos (as)*
5. *Primos (as), tíos (as), abuelos (as)*
6. *Amigos (as), vecinos (as), compadres, comadres, conocidos (as)*
7. *Otros (especificar)* _____

Sección I.4.- Asistencia a sesiones educativas, de auto cuidado o de auto ayuda

I.4.a.- ¿Ha asistido a grupos educativos, de auto cuidado o de auto ayuda en diabetes?
Si la respuesta a esta pregunta es 'No', escribir el código 9/99 en los ítems I.4.b al I.4.f. y pasar a la sección I.5.- Comorbilidad.

1. *Si* **2.** *No* ☐

I.4.b.- ¿Recuerda el nombre del grupo?

1. *Si* **2.** *No* **3.** *No aplica* ☐

Nombre: _____

I.4.c.- ¿Las sesiones a las que asistió fueron en el IMSS o en otra institución?
Especificar la institución solo en caso de que la respuesta del paciente sea: 'otra institución'.

1. *IMSS* **2.** *Especificar institución* ☐

3. *No aplica* _____

I.4.d.- ¿A cuántas sesiones asistió? ☐☐

I.4.e.- ¿Hace cuanto que asistió a la última sesión?:

1. *Un mes o menos* **2.** *Dos meses* **3.** *Tres meses* ☐
4. *Cuatro meses* **5.** *Cinco meses* **6.** *Seis meses*
7. *Siete meses o más*
9. *No aplica*

I.4.f.- ¿Qué tan útiles le parecieron las sesiones?

1. *Muy útiles* **2.** *Útiles* **3.** *Indiferente* ☐
4. *Poco útiles* **5.** *Muy poco útiles*

9. *No aplica*

Sección I.5.- Comorbilidad

Padece alguna de las siguientes enfermedades:

I.5.a.- Hipertensión ☐
1. *Si* **2.** *No*

I.5.b.- Eczema/dermatitis ☐
1. *Si* **2.** *No*

I.5.c.- Angina ☐
1. *Si* **2.** *No*

I.5.d.- Asma ☐
1. *Si* **2.** *No*

I.5.e.- Artritis / reumatismo ☐
1. *Si* **2.** *No*

I.5.f.- Depresión ☐
1. *Si* **2.** *No*

I.5.g.- Ulcera péptica / estomago o dispepsia ☐
1. *Si* **2.** *No*

I.5.h.- Gastritis ☐
1. *Si* **2.** *No*

I.5.i.- Osteoporosis ☐
1. *Si* **2.** *No*

I.5.j.- Insuficiencia cardiaca ☐
1. *Si* **2.** *No*

I.5.k.- Accidente cerebro vascular ☐
1. *Si* **2.** *No*

I.5.l.- Incontinencia urinaria ☐
1. *Si* **2.** *No*

I.5.m.- Insuficiencia renal ☐
1. *Si* **2.** *No*

I.5.n.- Obesidad ☐
1. *Si* **2.** *No*

I.5.o.- Herpes ☐
1. *Si* **2.** *No*

I.5.p.- Retinopatía diabética ☐
1. *Si* **2.** *No*

I.5.q.- Nefropatía diabética ☐
1. *Si* **2.** *No*

I.5.r.- Neuropatía diabética ☐
1. *Si* **2.** *No*

I.5.s.- Pie diabético ☐
1. *Si* **2.** *No*

II. Auto cuidado en diabetes

Sección II.1.- Escala de auto eficacia en diabetes

Con las siguientes preguntas nos gustaría saber qué piensa Ud. de sus habilidades para controlar su enfermedad. Por favor marque el número que mejor corresponda a su nivel de seguridad de que puede realizar en este momento las siguientes tareas.

II.1.a.- ¿Qué tan seguro(a) se siente Ud. de poder comer sus alimentos cada 4 ó 5 horas todos los días?(Esto incluye tomar desayuno todos los días)

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.b.- ¿Qué tan seguro(a) se siente Ud. de poder continuar su dieta cuando tiene que preparar o compartir alimentos con personas que no tienen diabetes?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.c.- ¿Qué tan seguro(a) se siente Ud. de poder escoger los alimentos apropiados para comer cuando tiene hambre (por ejemplo, bocadillos)?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.d.- ¿Qué tan seguro(a) se siente Ud. de poder hacer ejercicios de 15 a 30 minutos, unas 4 o 5 veces por semana?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.e.- ¿Qué tan seguro(a) se siente Ud. de poder hacer algo para prevenir que su nivel de azúcar en la sangre disminuya cuando hace ejercicios?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.f.- ¿Qué tan seguro(a) se siente Ud. de poder saber qué hacer cuando su nivel de azúcar en la sangre sube o baja más de lo normal para usted?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.g.- ¿Qué tan seguro(a) se siente Ud. de poder evaluar cuando los cambios en su enfermedad significan que usted debe visitar a su médico?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

II.1.h.- ¿Qué tan seguro(a) se siente Ud. de poder controlar su diabetes para que no interfiera con las cosas que quiere hacer?

muy seguro 1 2 3 4 5 6 7 8 9 10 muy inseguro

Sección II.2.- Cuestionario de conocimientos de la prescripción médica (MPKQ)

Con las siguientes preguntas nos interesa saber cómo toma usted los medicamentos que el médico familiar le indico en su última consulta.

II.2.a.- ¿Cual es el nombre del medicamento que el médico familiar le indico para la diabetes?

II.2.a.1.- El paciente refiere los siguientes medicamentos:

II.2.a.1.a.- Glibenclamida ☐
II.2.a.1.b.- Metformina ☐
II.2.a.1.c.- Acarbosa ☐
II.2.a.1.d.- Pioglitazona ☐
II.2.a.1.e.- Rosiglitazona ☐

1. Lo refiere **2.** *No lo refiere*

II.2.a.2.- El paciente conoce el nombre de los siguientes medicamentos:

II.2.a.2.a.- Glibenclamida ☐
II.2.a.2.b.- Metformina ☐
II.2.a.2.c.- Acarbosa ☐
II.2.a.2.d.- Pioglitazona ☐
II.2.a.2.e.- Rosiglitazona ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.b.- ¿Cuántas veces al día toma cada medicamento?

II.2.b.1.a.- El paciente refiere que consume glibenclamida en la siguiente frecuencia: ☐

1. Una vez al día (cada 24 horas)
2. Dos veces al día (cada 12 horas)
3. Tres veces al día (cada 8 horas)
4. *No recuerda o no sabe* **9.** *No aplica*

II.2.b.2.a.- El paciente conoce la frecuencia indicada de glibenclamida ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.b.1.b.- El paciente refiere que consume metformina en la siguiente frecuencia:

1. Una vez al día ☐

2. Dos veces al día

3. Tres veces al día

4. *No recuerda o no sabe* **9.** *No aplica*

II.2.b.2.b.- El paciente conoce la frecuencia indicada de metformina ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.b.1.c.- El paciente refiere que consume acarbosa en la siguiente frecuencia:

1. Una vez al día ☐

2. Dos veces al día

3. Tres veces al día

4. *No recuerda o no sabe* **9.** *No aplica*

II.2.b.2.c.- El paciente conoce la frecuencia indicada de acarbosa ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.b.1.d.- El paciente refiere que consume pioglitazona en la siguiente frecuencia:

1. Una vez al día ☐

2. Dos veces al día

3. Tres veces al día

4. *No recuerda o no sabe* **9.** *No aplica*

II.2.b.2.d.- El paciente conoce la frecuencia indicada de pioglitazona ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.b.1.e.- El paciente refiere que consume rosiglitazona en la siguiente frecuencia:

1. Una vez al día ☐

2. Dos veces al día

3. Tres veces al día

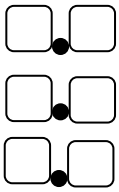
4. *No recuerda o no sabe* **9.** *No aplica*

II.2.b.2.e.- El paciente conoce la frecuencia indicada de rosiglitazona ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.c.- ¿Cuántas tabletas consume en cada toma?

II.2.c.1.a.- El paciente refiere que consume glibenclamida en la siguiente dosis:



½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

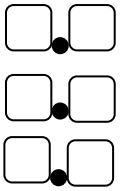
2 tabletas en cada toma (2.0)

5.0 *No recuerda o no sabe* **9.9** *No aplica*

II.2.c.2.a- El paciente conoce la dosis indicada de glibenclamida

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.c.1.b.- El paciente refiere que consume metformina en la siguiente dosis:



½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

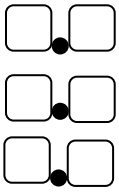
2 tabletas en cada toma (2.0)

5.0 *No recuerda o no sabe* **9.9** *No aplica*

II.2.c.2.b.- El paciente conoce la dosis indicada de metformina

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.c.1.c.- El paciente refiere que consume acarbosa en la siguiente dosis:



½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

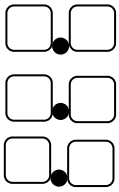
2 tabletas en cada toma (2.0)

5.0 *No recuerda o no sabe* **9.9** *No aplica*

II.2.c.2.c.- El paciente conoce la dosis indicada de acarbosa

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.c.1.d.- El paciente refiere que consume pioglitazona en la siguiente dosis:



½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

5.0 *No recuerda o no sabe* **9.9** *No aplica*

II.2.c.2.d.- El paciente conoce la dosis indicada de pioglitazona ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.c.1.e.- El paciente refiere que consume rosiglitazona en la siguiente dosis: ☐.☐

½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

5.0 *No recuerda o no sabe* **9.9** *No aplica*

II.2.c.2.e.- El paciente conoce la dosis indicada de rosiglitazona ☐

1. *Conoce* **2.** *No conoce* **9.** *No aplica*

II.2.d.- ¿El médico familiar le ha ofrecido tratamiento con insulina?

1. *Si* **2.** *No* ☐

II.2.e.- ¿Por qué no está tratándose con insulina?

Razón: _____ ☐☐

99. *No aplica*

Sección II.3.- Cuestionario de conocimientos en diabetes (DKQ-24)

Con las siguientes 24 preguntas nos gustaría saber que conocimientos tiene usted acerca de la diabetes. Le pedimos de favor nos responda 'Si' cuando considere que el enunciado es cierto, 'No' cuando considere que el enunciado es falso, o 'No se' cuando no esté seguro de si el enunciado es cierto o falso.

#	Preguntas	Si	No	No se
II.3.a.-	El comer mucha azúcar y otras comidas dulces es una causa de la diabetes.	0	1	0
II.3.b.-	La causa común de la diabetes es la falta de insulina efectiva en el cuerpo.	1	0	0
II.3.c.-	La diabetes es causada porque los riñones no pueden mantener el azúcar fuera de la orina.	0	1	0
II.3.d.-	Los riñones producen la insulina.	0	1	0
II.3.e.-	En la diabetes que no se está tratando, la cantidad de azúcar en la sangre usualmente sube.	1	0	0
II.3.f.-	Si yo soy diabético, mis hijos tendrán más riesgo de ser diabéticos.	1	0	0
II.3.g.-	Se puede curar la diabetes.	0	1	0
II.3.h.-	Un nivel de azúcar de 210 en prueba de sangre hecha en ayunas es muy alto.	1	0	0
II.3.i.-	La mejor manera de checar mi diabetes es haciendo pruebas de orina.	0	1	0
II.3.j.-	El ejercicio regular aumentará la necesidad de insulina u otro medicamento para la diabetes.	0	1	0
II.3.k.-	Hay dos tipos principales de diabetes: Tipo 1 (dependiente de insulina) y Tipo 2 (no-dependiente de insulina).	1	0	0
II.3.l.-	El nivel de azúcar en la sangre baja demasiado cuando las personas comen mucho	0	1	0
II.3.m.	La medicina es más importante que la dieta y el ejercicio pare controlar mi diabetes.	0	1	0
II.3.n.-	La diabetes frecuentemente causa mala circulación.	1	0	0
II.3.o.-	Cortaduras y rasguños cicatrizan más despacio en diabéticos.	1	0	0
II.3.p.-	Los diabéticos deberían poner cuidado extra al cortarse las uñas de los dedos de los pies.	1	0	0
II.3.q.-	Una persona con diabetes debería limpiar una cortadura primero con yodo y alcohol.	0	1	0
II.3.r.-	La manera en que preparo mi comida es igual de importante que las comidas que como.	1	0	0

#	Preguntas	Si	No	No se
II.3.s.-	La diabetes puede dañar mis riñones.	1	0	0
II.3.t.-	La diabetes puede causar que no sienta en mis manos, dedos y pies.	1	0	0
II.3.u.-	El temblar y sudar son señales de azúcar alta en la sangre.	0	1	0
II.3.v.-	El orinar seguido y la sed son señales de azúcar baja en la sangre.	0	1	0
II.3.w.	Los calcetines y las medias elásticas apretadas no son malos para los diabéticos.	0	1	0
II.3.x.-	Una dieta diabética consiste principalmente de comidas especiales.	0	1	0

Sección II.4.- Resumen de las actividades para el auto-cuidado de la diabetes (SDSCA)

Con las siguientes preguntas nos interesa saber sus actividades para el cuidado propio de la diabetes durante los últimos 7 días. Si usted estuvo enfermo/a en los últimos 7 días, por favor piense los últimos 7 días cuando no estaba enfermo. Elija el número que corresponde con su respuesta.

Dieta

II.4.a.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS ha seguido un plan de alimentación saludable?

0 1 2 3 4 5 6 7 ☐

II.4.b.- En promedio durante el último mes, ¿cuantos DÍAS POR SEMANA ha seguido su dieta saludable?

0 1 2 3 4 5 6 7 ☐

II.4.c.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS comió cinco o más raciones/porciones de frutas y verduras?

0 1 2 3 4 5 6 7 ☐

II.4.d.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS ha comido comidas grasosas, como carnes rojas u otras comidas grasosas como cremas o quesos?

0 1 2 3 4 5 6 7 ☐

II.4.e.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS distribuyó usted sus carbohidratos de manera uniforme durante el día?

0 1 2 3 4 5 6 7 ☐

Ejercicio

II.4.f.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS participó usted en por lo menos 30 minutos de actividad física? (Minutos totales de actividad que incluye caminar)

0 1 2 3 4 5 6 7 ☐

II.4.g.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS participó en una sesión específica de ejercicios (tales como natación, caminata, o ciclismo) aparte de lo que hace usted en su casa o como parte de su trabajo?

0 1 2 3 4 5 6 7 ☐

Prueba de Sangre

II.4.h.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS se hizo usted pruebas de azúcar en la sangre?

0 1 2 3 4 5 6 7 ☐

II.4.i.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS se hizo usted prueba de azúcar en la sangre el número de veces recomendados por su doctor?

0 1 2 3 4 5 6 7 ☐

Cuidado de los Pies

II.4.j.- ¿En cuántos de LOS ULTIMOS 7 DÍAS se chequeo/reviso sus pies?

0 1 2 3 4 5 6 7 ☐

Fumar

II.4.k.- ¿Ha fumado usted -aunque sea una inhalación- durante los últimos 7 DIAS?

0. No ☐

1. Si

II.4.l.- Si es así, ¿cuántos cigarros fuma usted en un día promedio?
Numero de cigarros ☐☐

Medicamentos

II.4.m.- ¿En cuántos de LOS ÚLTIMOS 7 DÍAS se tomó sus medicamentos recomendados para la diabetes?

0 1 2 3 4 5 6 7 ☐

III. Calidad de la atención en diabetes

Sección III.1.- Escala de continuidad de la atención del QuIP (Quality in Practice)

Las siguientes preguntas se refieren al médico familiar que regularmente lo atiende. Si usted no tiene un médico familiar que regularmente lo atienda, le pedimos de favor que responda las preguntas acerca del médico familiar que conoce mejor en el consultorio que le toca.

III.1.a ¿Qué tanto conoce al médico familiar que regularmente lo atiende?	Nada ☐ 1	Un poco ☐ 2	Algo ☐ 3	Bien ☐ 4	Muy bien ☐ 5	
III.1.b ¿A cuántos otros médicos de los que hay en su consultorio conoce usted <u>también</u>?	None ☐ 1	One ☐ 2	Two ☐ 3	Three ☐ 4	Four ☐ 5	Five o mas ☐ 6
III.1.c En general, ¿Qué tan seguido ve al médico familiar que regularmente lo atiende?	Siempre ☐ 1	Casi siempre ☐ 2	La mayor parte del tiempo ☐ 3	Algunas veces ☐ 4	Casi nunca ☐ 5	Nunca ☐ 6
III.1.d ¿Qué opina de las veces en que ve a su médico familiar?	Muy mal ☐ 1	Mal ☐ 2	Aceptable ☐ 3	Bien ☐ 4	Muy bien ☐ 5	Excelente ☐ 6

Sección III.2.- Escala de Comunicación Médico-Paciente (PDCS)

Con las siguientes 8 preguntas queremos saber la forma como **le trata** su médico familiar durante la consulta.

Le pedimos que piense en **TODAS** las consultas que ha recibido por su médico familiar y me responda las veces que a usted le pasa la experiencia que se le pregunta.

Item #. Preguntas	**Siempre**	**Casi siempre**	**Algunas veces**	**Casi nunca**	**Nunca**
III.2.a.- Su médico familiar le saluda amablemente	5	4	3	2	1
III.2.b.-Su médico familiar le pone atención mientras le explica lo que le pasa	5	4	3	2	1
III.2.c.- Mientras su médico familiar lo examina, le explica lo que le está haciendo	5	4	3	2	1
III.2.d.-El médico familiar le explica la razón por la cual el tratamiento es el mejor para usted	5	4	3	2	1
III.2.e.-Su médico familiar le da importancia a sus preguntas	5	4	3	2	1
III.2.f.-Su médico le da toda la información que usted espera	5	4	3	2	1
III.2.g.-Usted recomendaría su médico a sus amigos	5	4	3	2	1
III.2.h.-Le gustaría que este médico familiar le atendiera en sus próximas consultas	5	4	3	2	1

Sección III.3.- Cuestionario de Satisfacción del Paciente con la Atención de Diabetes (PSDC)

Con las siguientes 11 preguntas queremos saber su **opinión** respecto a las cosas que pueden hacer que usted se sienta **satisfecho** con la atención recibida en su consulta de medicina familiar

Item #. Preguntas	**Completamente de acuerdo**	**De acuerdo**	**Indiferente**	**En desacuerdo**	**Completamente en desacuerdo**
III.3.a.- Al ser consultado por su Médico Familiar esperaba usted que el azúcar en su sangre no estuviera alta	5	4	3	2	1
III.3.b.- Al ser consultado por su Médico Familiar esperaba que el tratamiento indicado fuera fácil de cumplir	5	4	3	2	1
III.3.c.- Cuando su Médico Familiar lo comenzó a tratar, usted esperaba que no le tomara mucho tiempo hacer lo que el Médico le indicó para controlar su Diabetes	5	4	3	2	1
III.3.d.- Al pedir una cita con su Médico Familiar usted esperaba que se la dieran en 2 días o antes	5	4	3	2	1
III.3.e.- Al pedir una cita con su Médico Familiar usted esperaba que le dieran su cita el mismo día	5	4	3	2	1
III.3.f.- Cuando acude con su Médico Familiar usted espera que le consulten sin haber hecho una cita	5	4	3	2	1
III.3.g.- Cuando acude con su Médico Familiar usted espera que su Médico le explique cuidadosamente cual es su problema con la diabetes	5	4	3	2	1
III.3.h.- Cuando acude con su Médico Familiar usted espera que su Médico le explique cuidadosamente todo lo que tiene que hacer para atender su diabetes	5	4	3	2	1
III.3.i.- Cuando acude con su Médico Familiar usted espera discutir todos sus problemas de salud con su Médico	5	4	3	2	1
III.3.j.- Cuando acude con su Médico Familiar usted espera que su Médico Familiar respete sus sentimientos	5	4	3	2	1
III.3.k.- Cuando acude a su consulta con su Médico Familiar usted espera que su Médico lo trate con respeto	5	4	3	2	1

Con las siguientes 11 preguntas queremos saber su **experiencia** respecto a las cosas que pueden hacer que usted se sienta **satisfecho** con la atención recibida en su consulta de medicina familiar.

Le pedimos que piense en **todas** las consultas que ha recibido por su médico familiar y responda las veces que a usted le pasa la experiencia que se le pregunta.

Item #. Preguntas	**Siempre**	**Casi siempre**	**Algunas veces**	**Casi nunca**	**Nunca**
III.3.l.- Con qué frecuencia en los exámenes de laboratorio el azúcar de su sangre se encuentra alta	1	2	3	4	5
III.3.m.- Con qué frecuencia encuentra dificultades para cumplir con el tratamiento indicado por su Médico Familiar	1	2	3	4	5
III.3.n.- Con qué frecuencia le toma mucho tiempo hacer lo que el Médico Familiar le indico para controlar su Diabetes	1	2	3	4	5
III.3.o.- Con qué frecuencia cuando pide una cita con su Médico Familiar tarda mas de dos días en atenderle	1	2	3	4	5
III.3.p.- Con que frecuencia cuando pide una cita con su Médico Familiar se la dan para el mismo día	5	4	3	2	1
III.3.q.- Con que frecuencia cuando acude a consulta con su Médico Familiar le consulta sin tener una cita	5	4	3	2	1
III.3.r.- Con que frecuencia su Médico Familiar le explica cuidadosamente cual es su problema con la diabetes	5	4	3	2	1
III.3.s.- Con que frecuencia su Médico Familiar le explica cuidadosamente todo lo que tiene que hacer para atender su diabetes	5	4	3	2	1
III.3.t.- Con que frecuencia usted puede discutir todos sus problemas de salud con su Médico Familiar	5	4	3	2	1
III.3.u.- Con que frecuencia su Médico Familiar NO respeta sus sentimientos	1	2	3	4	5
III.3.v.- Con que frecuencia en la consulta con su Médico Familiar usted siente que su Médico no lo respeta	1	2	3	4	5

IV.- Inventario de depresión de Beck

En este cuestionario aparecen situaciones que puede sentir, hacer o pensar en su vida diaria. Por favor escuche con atención cada una de ellas y señale cual de las situaciones de cada grupo describe mejor sus sentimientos durante la **ULTIMA SEMANA, INCLUIDO EL DIA DE HOY**. Asegúrese de haber escuchado todas las situaciones dentro de cada grupo antes de hacer la elección.

IV.a.- ☐

0. *No me siento triste*

1. *Me siento triste*

2. *Me siento triste continuamente y no puedo dejar de estarlo*

3. *Me siento tan triste o tan desgraciado (a) que no puedo soportarlo*

IV.b.- ☐

0. *No me siento especialmente desanimado (a) de cara al futuro*

1. *Me siento desanimando (a) de cara al futuro*

2. *Siento que no hay nada por lo que luchar*

3. *El futuro es desesperanzador y las cosas no mejoran*

IV.c.- ☐

0. *No me siento como un (a) fracasado (a)*

1. *He fracasado más que la mayoría de las personas*

2. *Cuando miro hacia atrás, lo único que veo es un fracaso tras otro*

3. *Soy un fracaso total como persona*

IV.d.- ☐

0. *Las cosas me satisfacen tanto como antes*

1. *No disfruto las cosas tanto como antes*

2. *Yo no tengo ninguna satisfacción de las cosas*

3. *Estoy insatisfecho o aburrido con respecto a todo*

IV.e.-

0. *No me siento especialmente culpable*

1. *Me siento culpable en bastantes ocasiones*

2. *Me siento culpable en la mayoría de las ocasiones*

3. *Me siento culpable constantemente*

IV.f.-

0. *No creo que este siendo castigado (a)*

1. *Siento que quizás esté siendo castigado (a)*

2. *Espero ser castigado (a)*

3. *Siento que estoy siendo castigado (a)*

IV.g.-

0. *No estoy descontento (a) de mi mismo (a)*

1. *Estoy descontento (a) de mí mismo (a)*

2. *Estoy a disgusto conmigo mismo (a)*

3. *Me detesto*

IV.h.-

0. *No me considero peor que cualquier otro (a)*

1. *Me autocritico por mi debilidad o por mis errores*

2. *Continuamente me culpo por mis faltas*

3. *Me culpo por todo lo malo que sucede*

IV.i.-

0. *No tengo ningún pensamiento de suicidio*

1. *A veces pienso en suicidarme pero no lo haré*

2. *Desearía poner fin a mi vida*

3. *Me suicidaría si tuviese oportunidad*

IV.j.-

0. *No lloro más de lo normal*

1. *Ahora lloro más que antes*

2. *Lloro continuamente*

3. *No puedo dejar de llorar aunque me lo proponga*

IV.k.-

0. *No estoy especialmente molesto (a)*

1. *Me molesto más fácilmente que antes*

2. *Me molesto continuamente*

3. *Ahora no me molestan en absoluto cosas que antes me molestaban*

IV.l.-

0. *No he perdido el interés por los demás*

1. *Estoy menos interesado (a) en los demás que antes*

2. *He perdido gran parte del interés por los demás*

3. *He perdido todo interés por los demás*

IV.m.-

0. *Tomo mis propias decisiones igual que antes*

1. *Evito tomar decisiones más que antes*

2. *Tomar decisiones me resulta mucho más difícil que antes*

3. *Me es imposible tomar decisiones*

IV.n.-

0. *No creo tener peor aspecto que antes*

1. *Estoy preocupado (a) porque parezco envejecido (a) y poco atractivo (a)*

2. *Noto cambios constantes en mi aspecto físico que me hacen parecer poco atractivo (a)*

3. *Creo que tengo un aspecto horrible*

IV.o.-

0. *Trabajo igual que antes*

1. *Me cuesta más esfuerzo de lo habitual comenzar a hacer algo*

2. *Tengo que obligarme a mi mismo (a) para hacer algo*

3. *Soy incapaz de llevar a cabo ninguna tarea*

IV.p.-

0. *Duermo tan bien como siempre*

1. *No duermo tan bien como antes*

2. *Me despierto 1-2 hr antes de lo habitual y me cuesta volverme a dormir*

3. *Me despierto varias horas antes de lo habitual y ya no puedo volverme a dormir*

IV.q.-

0. *Me siento más cansado(a) de lo normal*

1. *Me canso más que antes*

2. *Me canso en cuanto hago cualquier cosa*

3. *Estoy demasiado cansado (a) para hacer nada*

IV.r.-

0. *Mi apetito no ha disminuido*

1. *No tengo tan buen apetito como antes*

2. *Ahora tengo mucho menos apetito*

3. *He perdido completamente el apetito*

IV.s.-

0. *No he perdido peso últimamente*

1. *He perdido más de 2 kilogramos*

2. *He perdido más de 4 kilogramos*

3. *He perdido más de 7 kilogramos*

IV.t.-

0. *No estoy preocupado (a) por mi salud*

1. *Me preocupan los problemas físicos, como dolores, malestar de estómago o los catarros, etc.*

2. *Me preocupan las enfermedades y me resulta difícil pensar en otras cosas*

3. *Estoy tan preocupado (a) por las enfermedades que soy incapaz de pensar en otras cosas*

IV.u.-

0. *No he observado ningún cambio en mi interés por el sexo*

1. *La relación sexual me atrae menos que antes*

2. *Estoy mucho menos interesado (a) por el sexo que antes*

3. *He perdido totalmente el interés sexual*

TOTAL

V.- Información recolectada del expediente clínico electrónico

Sección V.1.- Tensión arterial

V.1.a.- Sistólica ☐☐☐ V.1.b.- Diastólica ☐☐☐

Sección V.2.- Continuidad de la atención

V.2.a.- Fecha de última consulta: ☐☐ ☐☐ ☐☐☐☐
DIA *MES* *AÑO*

V.2.b.- Numero de consultas de control de diabetes en los últimos 6 meses ☐☐

V.2.c.- Numero de consultas de control de diabetes con el mismo médico familiar en los últimos 6 meses ☐☐

V.2.d.- Numero de médicos familiares que otorgaron las consultas de control de diabetes en los últimos 6 meses ☐☐

Sección V.3.- Intensificación del tratamiento farmacológico

Fecha y valores registrados en el expediente clínico electrónico de: hemoglobina glucosilada, glucosa en ayunas, e IMC. *Se tomaran los datos de este apartado de la consulta con fecha de 2 meses previos a la invitación del paciente.*
Nota: puede ser que en esa consulta no se encuentren los 3 valores, entonces se pueden tomar de diferentes citas mientras que correspondan al periodo de 2 a 6 meses previos a la invitación del paciente en el proyecto.

V.3.a.- Fecha en que se registro la HbA1c ☐☐ ☐☐ ☐☐☐☐
DIA *MES* *AÑO*

V.3.b.- Nivel de hemoglobina glucosilada ☐☐.☐☐

V.3.c.- Fecha en que se registró la glucosa en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA *MES* *AÑO*

V.3.d.- Nivel de glucosa en ayunas ☐☐☐.☐☐

V.3.e.- Fecha en que se registró el IMC ☐☐ ☐☐ ☐☐☐☐
DIA *MES* *AÑO*

V.3.f.- Nivel de IMC ☐☐.☐☐

Sección V.4.a.- Prescripción medica

Se tomaran los datos de este apartado de la consulta con fecha de 2 a 6 meses previos a la invitación del paciente. Utilizando los códigos de la sección V.4. Prescripción medica.

Nombre del medicamento		**Frecuencia de consumo**	
Glibenclamida	☐	Glibenclamida	☐
Metformina	☐	Metformina	☐
Acarbosa	☐	Acarbosa	☐
Pioglitazona	☐	Pioglitazona	☐
Rosiglitazona	☐	Rosiglitazona	☐

Cantidad del medicamento

Glibenclamida	☐☐.☐	☐☐.☐	☐☐.☐
Metformina	☐☐.☐	☐☐.☐	☐☐.☐
Acarbosa	☐☐.☐	☐☐.☐	☐☐.☐
Pioglitazona	☐☐.☐	☐☐.☐	☐☐.☐
Rosiglitazona	☐☐.☐	☐☐.☐	☐☐.☐

Sección V.4.- Prescripción medica

Identificar en el expediente clínico de medicina familiar la indicación farmacológica que el médico familiar prescribió al paciente diabético. Escribir el código que corresponda a la información escrita en el expediente clínico del paciente.

V.4.a.- Medicamentos prescritos

V.4.a.1.-.Glibenclamida	☐
V.4.a.2.- Metformina	☐
V.4.a.3.- Acarbosa	☐
V.4.a.4.- Pioglitazona	☐
V.4.a.5.- Rosiglitazona	☐

1. *Indicado* **2.** *No indicado* **9.** *No aplica*

V.4.b.- Frecuencia de consumo de medicamentos por día ☐

V.4.b.1.- Glibenclamida

1. Una vez al día (cada 24 horas)

2. Dos veces al día (cada 12 horas)

3. Tres veces al día (cada 8 horas)

9. No aplica

V.4.b.2.- Metformina ☐

1. Una vez al día (cada 24 horas)

2. Dos veces al día (cada 12 horas)

3. Tres veces al día (cada 8 horas)

9. No aplica

V.4.b.3.- Acarbosa ☐

1. Una vez al día (cada 24 horas)

2. Dos veces al día (cada 12 horas)

3. Tres veces al día (cada 8 horas)

9. No aplica

V.4.b.4.- Pioglitazona ☐

1. Una vez al día (cada 24 horas)

2. Dos veces al día (cada 12 horas)

3. Tres veces al día (cada 8 horas)

9. No aplica

V.4.b.5.- Rosiglitazona

1. Una vez al día (cada 24 horas)

2. Dos veces al día (cada 12 horas) ☐

3. Tres veces al día (cada 8 horas)

9. No aplica

V.4.c.- Dosis de cada medicamento por toma

V.4.c.1.- Glibenclamida

½ tableta en cada toma (0.5)

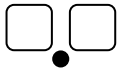
1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

9.9. *No aplica*

V.4.c.2.- Metformina



½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

9.9. *No aplica*

V.4.c.3.- Acarbosa

½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

9.9. *No aplica*

V.4.c.4.- Pioglitazona

½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

9.9. *No aplica*

V.4.c.5.- Rosiglitazona

½ tableta en cada toma (0.5)

1 tableta en cada toma (1.0)

1 ½ tabletas en cada toma (1.5)

2 tabletas en cada toma (2.0)

9.9. *No aplica*

V.4.d.- El paciente requiere intensificación de tratamiento farmacológico

1. *Si* **2.** *No* **9.** *No existe información para valorar si el paciente requiere intensificación del tratamiento farmacológico (información de: hemoglobina glucosilada, glucosa en ayunas, y/o prescripción farmacológica)*

V.4.e.- El medico familiar intensifica tratamiento farmacológico

1. *Si*

2. *No*

3. *El médico familiar no intensifica porque no se requiere*

4. *El médico familiar intensifica aunque no se requiere*

9. *No existe información para valorar si el médico familiar requiere intensificar el tratamiento farmacológico (información de: hemoglobina glucosilada, glucosa en ayunas, y/o prescripción farmacológica)*

Sección V.5.- Mediciones de hemoglobina glucosilada

V.5.a.- Número de veces en que se registro la hemoglobina glucosilada en el expediente electrónico los últimos 12 meses

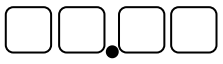
Registrar las fechas en que se registro la hemoglobina glucosilada, *comenzando con la fecha más reciente*

V.5.a.1.- Fecha 1 en que se registró la hemoglobina glucosilada *DIA MES AÑO*

V.5.a.2.- Nivel de hemoglobina glucosilada

V.5.a.3.- Fecha 2 en que se registró la hemoglobina glucosilada

V.5.a.4.- Nivel de hemoglobina glucosilada



V.5.a.5.- Fecha 3 en que se registró la hemoglobina glucosilada

V.5.a.6.- Nivel de hemoglobina glucosilada

V.5.a.7.- Fecha 4 en que se registró la hemoglobina glucosilada

V.5.a.8.- Nivel de hemoglobina glucosilada

V.5.a.9.- Fecha 5 en que se registró la hemoglobina glucosilada

V.5.a.10.- Nivel de hemoglobina glucosilada

V.5.a.11.- Fecha 6 en que se registró la hemoglobina glucosilada

V.5.a.12.- Nivel de hemoglobina glucosilada

V.5.a.13.- Fecha 7 en que se registró la hemoglobina glucosilada

V.5.a.14.- Nivel de hemoglobina glucosilada

V.5.a.15.- Fecha 8 en que se registró la hemoglobina glucosilada

V.5.a.16.- Nivel de hemoglobina glucosilada

V.5.a.17.- Fecha 9 en que se registró la hemoglobina glucosilada

V.5.a.18.- Nivel de hemoglobina glucosilada

V.5.a.19.- Fecha 10 en que se registró la hemoglobina glucosilada

V.5.a.20.- Nivel de hemoglobina glucosilada

V.5.a.21.- Fecha 11 en que se registró la hemoglobina glucosilada

V.5.a.22.- Nivel de hemoglobina glucosilada ☐☐.☐☐

V.5.a.23.- Fecha 12 en que se registró la hemoglobina glucosilada ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.5.a.24.- Nivel de hemoglobina glucosilada ☐☐.☐☐

Sección V.6.- Mediciones de glucosa sanguínea en ayunas

V.6.a.- Número de veces en que se registro la glucosa sanguínea en ayunas en el expediente electrónico los últimos 12 meses ☐☐

Registrar las fechas en que se registro la hemoglobina glucosilada, *comenzando con la fecha más reciente*

V.6.a.1.- Fecha 1 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.2.- Nivel de glucosa en ayunas ☐☐☐.☐☐

V.6.a.3.- Fecha 2 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.4.- Nivel de glucosa en ayunas ☐☐☐.☐☐

V.6.a.5.- Fecha 3 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.6.- Nivel de glucosa en ayunas ☐☐☐.☐☐

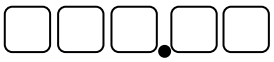
V.6.a.7.- Fecha 4 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.8.- Nivel de glucosa en ayunas ☐☐☐.☐☐

V.6.a.9.- Fecha 5 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.10.- Nivel de glucosa en ayunas ☐☐☐.☐☐

V.6.a.11.- Fecha 6 en que se registró la glucosa sanguínea en ayunas ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

V.6.a.12.- Nivel de glucosa en ayunas 

V.6.a.13.- Fecha 7 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.14.- Nivel de glucosa en ayunas 

V.6.a.15.- Fecha 8 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.16.- Nivel de glucosa en ayunas 

V.6.a.17.- Fecha 9 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.18.- Nivel de glucosa en ayunas 

V.6.a.19.- Fecha 10 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.20.- Nivel de glucosa en ayunas 

V.6.a.21.- Fecha 11 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.22.- Nivel de glucosa en ayunas 

V.6.a.23.- Fecha 12 en que se registró la glucosa sanguínea en ayunas 
DIA MES AÑO

V.6.a.24.- Nivel de glucosa en ayunas 

VI.- Información recolectada de los exámenes de laboratorio

VI.a.- Fecha de examen de laboratorio ☐☐ ☐☐ ☐☐☐☐
DIA MES AÑO

VI.b.- Hemoglobina glucosilada ☐☐.☐☐

VI.c.- Glucosa en ayunas ☐☐☐.☐☐

VI.d.- Colesterol total ☐☐☐.☐☐

VI.e.- Triglicéridos ☐☐☐.☐☐

Mes	Fecha de consulta	Matricula	Glucosa/ HbA1c	Mes	Fecha de consulta	Matricula	Glucosa/ HbA1c

Appendix 8.5 Participant information sheet and consent forms – English and Spanish versions

MANCHESTER 1824

The University of Manchester

Self-management, quality of care and glycaemic control in patients with type 2 diabetes

Participant Information Sheet

You are being invited to take part in a research study.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Who is conducting the research?

The research is being conducted by the Mexican Institute of Social Security, working with the Primary Care Research Group at the University of Manchester, United Kingdom.

What is the aim of the research?

We are looking at what factors improve blood sugar control in patients with diabetes. These factors might include patient's self-management (e.g. diet and exercise) and the care provided by their doctors.

Why have I been chosen?

You were chosen because you have diabetes and are being cared for by doctors in the Mexican Institute of Social Security. We are asking 400 patients to take part.

What would I be asked to do if I took part?

We will ask you questions about you and your background, how you manage your diabetes, and your views about the care you receive from your doctor.

We will ask you for the following information:

- ⇨ your background
- ⇨ how often you see your registered doctor
- ⇨ your opinion about the care you receive from your doctor
- ⇨ whether you have attended health education
- ⇨ your knowledge about diabetes
- ⇨ how you manage your diabetes
- ⇨ how diabetes affects you and the way you feel

We will also ask you to attend a laboratory appointment in the hospital. A clinical chemist will take a blood sample to analyse the sugar level in your blood. You might

feel some discomfort when the chemist takes the sample and afterwards, you might have a bruise.

How is confidentiality maintained?

All the information which we collect about you during the course of the study will remain completely confidential, and will not be discussed with anyone else. We will make sure that your personal details are protected.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason, and it will not affect the way you are treated in future.

Will I be paid for participating in the research?

There is no payment for taking part in the research.

What is the duration of the research?

You will spend 30-60 minutes answering questions and 30 minutes in the laboratory appointment at the beginning of the study, and the same amount of time 6 months later.

Where will the research be conducted?

You will be asked to answer the questionnaires in the family medicine clinic where you are registered. The laboratory appointment will be in the hospital.

Will the outcomes of the research be published?

The outcomes of this research will be published in a scientific journal.

Contact for further information

Yolanda Martinez
Epidemiological and Health Services Research Centre, Mexican Institute of Social Security, Av. de la Convención s/n Colonia Lindavista, C.P. 20270, Aguascalientes, Ags., Mexico (Tel: + 52 449 9139050 ext 41724; Fax/tel: + 52 449 9789400; email: Yolanda.Martinez@postgrad.manchester.ac.uk).

What if something goes wrong?

If the events of problems please contact:

Carlos Prado
Head of the Epidemiological and Health Services Research Centre.
Mexican Institute of Social Security, Av. de la Convención s/n Colonia Lindavista, C.P. 20270, Aguascalientes, Ags., Mexico (Tel: + 52 449 9139050 ext 41724; Fax/tel: + 52 449 9789400; email: carlospa@uiessags.com).

MANCHESTER 1824

The University of Manchester

Self-management, quality of care and glycaemic control in patients with type 2 diabetes

CONSENT FORM

If you are happy to participate please complete and sign the consent form below

	Please Initial Box
1. I confirm that I have read the attached information sheet on the above project and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to any treatment/service	

I agree to take part in the above project

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Consent Form to Participate in Clinical Research Studies at MISS

Place and date Aguascalientes, Ags.,

I accept to participate in the following research study:
Self-management, quality of care, and glycaemic control in patients with type 2 diabetes

Approved by the Local Research Committee Nº 101 with reference number: R-2009-101-12

The aim of the research is:
We are looking at what factors improve blood sugar control in patients with diabetes. These factors might include patient's self-management (e.g. diet and exercise) and the care provided by their doctors.

If I took part I would be asked to do:
Answer questions about the following information:

My background, how often I see my registered doctor, my opinion about the care I receive from my doctor, whether I have attended health education my knowledge about diabetes, how I manage my diabetes, how diabetes affects me and the way I feel.

I will also be asked to attend a laboratory appointment in the hospital. A clinical chemist will take a blood sample to analyse the sugar level in my blood. I might feel some discomfort when the chemist takes the sample and afterwards, I might have a bruise.

I was informed about risks, pain, discomfort, or benefits, if any, that I may experience among which are the following:

There is not any risk of my participation in this study. I may feel pain when the clinical chemist takes the blood sample. The discomfort may be the time I will spend answering the questions and going to the laboratory appointment in the hospital at the beginning of the study and 6 months later (30-60 minutes answering the questions and 30 minutes in the hospital). The benefit will be the laboratory evaluations including tests are not evaluated routinely. These tests will be delivered to my registered doctor at the end of the study.

The researcher in charge made sure to answer any question or doubt I have about study procedures, risks, benefits or any other issue related with the study.
I understand that I have the right to withdraw at any time without giving a reason, and it will not affect the way I am treated in future.
All the information is collected about me during the course of the study will remain completely confidential, and will not be discussed with anyone else. The researcher in charge will make sure that my personal details are protected.

Name and signature of participant

Yolanda Veronica Martinez, Mat.
99011494

Name, signature, and ID of researcher in charge

Participants can call the following telephone numbers in case of an emergency, doubts, or questions related to the study:
Tel and fax (449) 9789400. Tel (449) 9139050 ext. 41724

Witnesses

Clave: 2810 – 009 – 013

MANCHESTER 1824

The University of Manchester

Auto cuidado, calidad de la atención y control glucémico en pacientes con diabetes tipo 2

Carta de informacion para el participante

Se le invita a participar en este proyecto de investigación.

Antes de que usted decida participar, es importante que entienda por qué se está realizando esta investigación y en que consiste. Le pedimos de favor tome el tiempo suficiente para leer cuidadosamente la siguiente información y sienta la libertad de discutirla con otras personas si usted lo desea.

Le pedimos de favor que si cualquier cosa no esta clara o si le gustaría tener mas información nos pregunte. Tome el tiempo necesario para decidir si o no desea participar en el proyecto de investigación. Le agradecemos que lea esta información.

¿Quien esta realizando la investigación?

La investigación la esta realizando el Instituto Mexicano del Seguro Social en colaboración con el grupo de Investigación en Atención Primaria de la Universidad de Manchester, Reino Unido.

¿Cuál es el objetivo de la investigación?

Nosotros estamos buscando que factores mejoran el control de la azúcar en la sangre en pacientes con diabetes. Estos factores podrían incluir el auto cuidado del paciente (por ejemplo, dieta y ejercicio) y la atención proporcionada por los médicos.

¿Por qué he sido elegido?

Usted fue elegido porque tiene diabetes y es atendido por los médicos del Instituto Mexicano del Seguro Social. Nosotros estamos solicitando la participación de 400 pacientes.

¿Qué tendría que hacer si decidiera participar?

Nosotros le haríamos preguntas acerca de sus antecedentes, de cómo controla su diabetes, y de sus opiniones acerca de la atención que recibe de su medico.

También le pediríamos que atendiera una cita de laboratorio en el hospital al que pertenece. En el laboratorio, un químico le tomara una muestra de sangre para analizar el nivel de azúcar en su sangre. Usted podría sentir algún malestar cuando el químico le tome la muestra, y posteriormente, usted podría presentar un morete en el lugar en que le tomaron la muestra.

¿Cómo se mantiene la confidencialidad?

Toda la información que se colecte acerca de usted durante el estudio permanecerá completamente confidencial, y no se discutirá con nadie más. Nosotros nos aseguraremos de que sus detalles personales sean protegidos.

¿Qué sucede si no quiero participar o si cambio de opinión?

Depende de usted si quiere participar o no en el proyecto. Si usted decide participar se le entregara esta información para que la conserve y se le solicitara que firme una carta de consentimiento informado. Si decide participar siéntase libre de dejar el proyecto en cualquier momento sin dar ninguna explicación y su decisión no afectara la atención que se le brinde en el futuro.

¿Recibiré dinero por participar en la investigación?

No existe ningún pago por participar en la investigación.

¿Cuál es la duración de la investigación?

Se le solicita que usted dedique de 30 a 60 minutos respondiendo las preguntas y 30 minutos en la cita de laboratorio al inicio del estudio, y la misma cantidad de tiempo 6 meses después.

¿En donde se realizara la investigación?

Se le pedirá que responda los cuestionarios en la Unidad de Medicina Familiar al que está adscrito y en una visita que se realizara en su domicilio. La cita de laboratorio será en el hospital.

¿Los resultados de la investigación serán publicados?

Los resultados de la investigación serán publicados en una revista científica.

Para más información contactar

Yolanda Martínez
Unidad de Investigación Epidemiológica y en Servicios de Salud
Instituto Mexicano del Seguro Social
Av. de la Convención s/n Colonia Lindavista, C.P.20180
Aguascalientes, Ags., Mexico
Tel y fax: (449) 9789400

¿Qué hacer si existe algún problema?
Si existe algún problema le pedimos de favor se comunique con:

Carlos Prado
Jefe de la Unidad de Investigación Epidemiológica y en Servicios de Salud
Instituto Mexicano del Seguro Social
Av. de la Convención s/n Colonia Lindavista, C.P.20180
Aguascalientes, Ags., Mexico
Tel y fax: (449) 9789400

Auto cuidado, calidad de la atención y control glucémico en pacientes con diabetes tipo 2

CARTA DE CONSENTIMIENTO

Si usted está de acuerdo en participar le pedimos de favor complete y firme esta carta de consentimiento.

Favor de escribir sus iniciales en cada cuadro.

	Iniciales
3. Confirmo que he leído la hoja de información para el participante adjunta y relacionada a este proyecto y he tenido la oportunidad de considerar la información y hacer preguntas y estoy satisfecho con las respuestas que obtuve.	
4. Entiendo que mi participación en el estudio es voluntaria y que soy libre de retirarme del estudio en cualquier momento sin dar ninguna razón y sin que se afecte cualquier tratamiento o servicio que recibo.	

Estoy de acuerdo en participar en este proyecto

Nombre del participante	Fecha	Firma
Nombre de la persona que toma el consentimiento	Fecha	Firma

Carta de Consentimiento Informado para Participación en Protocolos de Investigación Clínica

Lugar y Fecha Aguascalientes, Ags., a de 20__

Por medio de la presente acepto participar en el protocolo de investigación titulado: Auto cuidado y calidad de la atención como predictores del control glucémico en pacientes con diabetes tipo 2

Registrado ante el Comité Local de Investigación con el número:R-2009-101-12

El objetivo del estudio es: Identificar los factores que mejoran el control del azúcar en sangre en pacientes con diabetes. Estos factores pueden incluir el auto cuidado de la diabetes que realiza el paciente (por ejemplo la dieta y el ejercicio) y la atención proporcionada por los médicos.

Se me ha explicado que mi participación consistirá en:

Contestar 8 cuestionarios acerca de sus datos generales, estado de animo, conocimientos acerca de la diabetes y el tratamiento medico, actividades que realiza para el auto cuidado de la diabetes, la confianza que tiene para controlar la diabetes, su opinión acerca de la comunicación entre usted y su medico, y la satisfacción con la atención que recibe para el control de la diabetes por parte del medico familiar.

Declaro que se me ha informado ampliamente sobre los posibles riesgos, inconvenientes, molestias y beneficios derivados de mi participación en el estudio, que son los siguientes: La participación en este proyecto de investigación no implica ningún riesgo. Los posibles inconvenientes o molestias serán el tiempo que dedique en contestar los cuestionarios el cual se estima será de alrededor de 60 minutos y acudir a un examen de laboratorio en el que se le tomara una muestra sanguínea. Estos procedimientos se realizaran en 2 ocasiones, al inicio de este estudio y de nuevo a los 6 meses. El beneficio derivado de su participación será el de contar con una evaluación laboratorial mas minuciosa de la que rutinariamente se le solicita.

El Investigador Responsable se ha comprometido a darme información oportuna sobre cualquier procedimiento alternativo adecuado que pudiera ser ventajoso para mi tratamiento, así como a responder cualquier pregunta y aclarar cualquier duda que le plantee acerca de los procedimientos que se llevarán a cabo, los riesgos, beneficios o cualquier otro asunto relacionado con la investigación o con mi tratamiento. Entiendo que conservo el derecho de retirarme del estudio en cualquier momento en que lo considere conveniente, sin que ello afecte la atención médica que recibo en el Instituto. El Investigador Responsable me ha dado seguridades de que no se me identificará en las presentaciones o publicaciones que deriven de este estudio y de que los datos relacionados con mi privacidad serán manejados en forma confidencial. También se ha comprometido a proporcionarme la información actualizada que se obtenga durante el estudio, aunque esta pudiera cambiar de parecer respecto a mi permanencia en el mismo.

_____

Nombre y firma del paciente

MCSS Yolanda Verónica Martínez,
Mat. 99011494

_____

Nombre, firma y matrícula del Investigador Responsable.

Números telefónicos a los cuales puede comunicarse en caso de emergencia, dudas o preguntas relacionadas con el estudio:

Teléfono directo y fax (449) 9789400. Teléfono (449) 9139050 ext. 41724

Testigos

_____ _____

Clave: 2810 – 009 – 013

Appendix 8.6 Ethical approval letters

MANCHESTER
1824

The University of Manchester

Secretary to the Ethics Committee
Room 2.005 John Owens Building

Tel: 0161 275 2206/2046
Fax: 0161 275 5697
Email: timothy.stibbs@manchester.ac.uk

Office of the Registrar and Secretary
University of Manchester
Oxford Road
Manchester, M13 9PL

ref: TPCS/ethics/09121

Ms Yolanda Martinez,
Primary Care Research Group,
School of Community Based Medicine

17th July 2009

Dear Yolanda,

Committee on the Ethics of Research on Human Beings
Martinez: Self management and quality of care as predictors of glycaemic control in patients with type 2 diabetes (ref 09121)

I write to thank you and Peter Bower for coming to meet the Committee on Monday and to confirm that the Committee gave ethical approval to the above project, subject to the following:

> Submitting a revised information sheet. This should provide more information, particularly on what participants are expected to do, what, in summary, will be in the questionnaires and how participants can obtain further information from you.

I will email you a model information sheet. I would be grateful if you could send me your revised document which we will be able to consider without waiting for the next committee meeting.

The Committee noted that you will also be seeking ethical app0roval from the appropriate Mexican authorities.

Yours sincerely,

Timothy Stibbs

Dr T P C Stibbs
Secretary to the Committee

cc. Dr Peter Bower

INSTITUTO MEXICANO DEL SEGURO SOCIAL
SEGURIDAD Y SOLIDARIDAD SOCIAL

DELEGACIÓN ESTATAL EN AGUASCALIENTES
JEFATURA DE PRESTACIONES MÉDICAS
COORDINACION DE INVESTIGACIÓN EN SALUD

"2009, **Año de la Reforma Liberal '**

Aguascalientes, Ags., a 06 de Agosto de 2009.

OFICIO No. 019001 2801100/006/2009

Dr. Carlos Alberto Prado Aguilar
Investigador Responsable de la UIESS

Por este conducto me permito informar a Usted que, el protocolo de investigación en salud presentado cuyo título es: "Auto cuidado y calidad de la atención como **predictores** del control **glucèmico** en pacientes *con* **diabetes** tipo **2"** y que forma parte de un proyecto de tesis de posgrado de la C. Yolanda Verónica Martinez, quién desarrolla Doctorado en Atención Primaria en Salud en la Universidad de Manchester, Reino Unido, fue sometido a consideración del Comité Local de Investigación en Salud, quién de acuerdo con las recomendaciones de sus integrantes y de los revisores consideraron que cumple con la calidad metodológica y los requerimientos de ética médica y de investigación vigentes, por lo que el dictamen emitido fue de : A U T *O* R I Z A D O.

Habiéndose asignado el siguiente número de registro Institucional:

R-2009-101-12

Atentamente

Dr. Juan Francisco Jiménez González
Presidente del Comité Local de Investigación en Salud Núm. 101

IMSS
SEGURIDAD Y SOLIDARIDAD SOCIAL

Av. de la Convención s/n casi esquina con Blvd. José Ma. Chavez. Aguascalientes. Ags. C.P.20270
Tel. (449) 978 94 00
Correo electrónico: jjmldivia@uiessags.com

MEXICAN INSTITUTE OF SOCIAL SECURITY
SOCIAL SECURITY AND SOLIDARITY

STATE DELEGATION IN AGUASCALIENTES
OFFICE OF MEDICAL BENEFITS
HEALTH RESEARCH HEADQUARTERS

"2009, The Year of Liberal Reform"

Aguascalientes, Ags., August 6, 2009

OFFICIAL DOCUMENT No.019001 2801100/006/2009

Dr. Carlos Alberto Prado Aguilar
Principal Researcher at the UIESS (*Epidemiological and Health Services Research Unit*)

I am writing to inform you that the health research protocol titled "Self-care and quality of attention as predictors of glycemic control in patients with Type 2 diabetes" (which forms part of a postgraduate thesis project by Ms. Yolanda Verónica Martínez, who is currently undertaking a doctoral programme in Primary Health Care at the University of Manchester in the United Kingdom) was submitted for the consideration of the Local Health Research Committee, whose view it was, based on the recommendations of its members and reviewers, that such protocol does indeed meet the methodological quality and current requirements of medical ethics and research. Therefore, the decision issued in this regard was that of: **AUTHORISED**.

The aforementioned decision is recorded in the institutional register under the following number:

R-2009-101-12

Sincerely yours

[*illegible signature*]
Dr. Juan Francisco Jiménez González
Chairman of Local Health Research Committee N° 101

IMSS
SOCIAL SECURITY AND SOLIDARITY

Av. de la Convención s/n casi esquina con Blvd. José Ma. Chávez
Aguascalientes, Ags. C.P. 20270

Phone: (449) 978 94 00
E-mail: jjmldivla@uiessags.com

Beatriz Elena Meza Cuervo
English-Spanish-English Translator and Interpreter
Certified Member of the Mexican Translators Association
Certified Expert for the Supreme Court of the State of Gto.

peritos TRADUCTORES s.c.

I, Beatriz Elena Meza Cuervo, a duly authorized English-Spanish-English translator, designated as such by the Judicial Branch of the State Government of Guanajuato, Mexico, do hereby certify that this attached document is a true, exact, and complete translation of the original in Spanish of the following:

- **Letter issued by the Mexican Institute of Social Security (IMSS, its acronym in Spanish) authorising the health research protocol submitted by Ms. Yolanda Verónica Martínez.**

Moreover, I certify that the translation was prepared based on a digital file submitted in .pdf format, which I received by e-mail, and which seems to be authentic and unaltered. The English version consists of ONE (1) page of printed text, which bears the signature and seal of the translator. The original document bears an illegible signature.

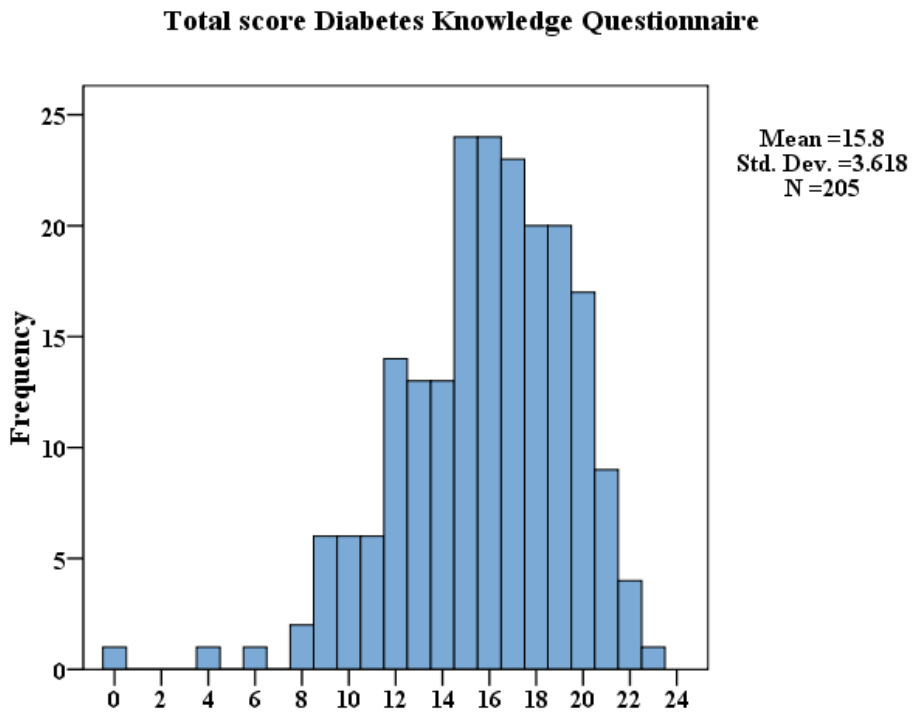
Witness my hand and seal, in the city of León, Mexico, on this 17th day of August, 2009.

ELENA MEZA CUERVO
PERITO TRADUCTORA
DE GTO.

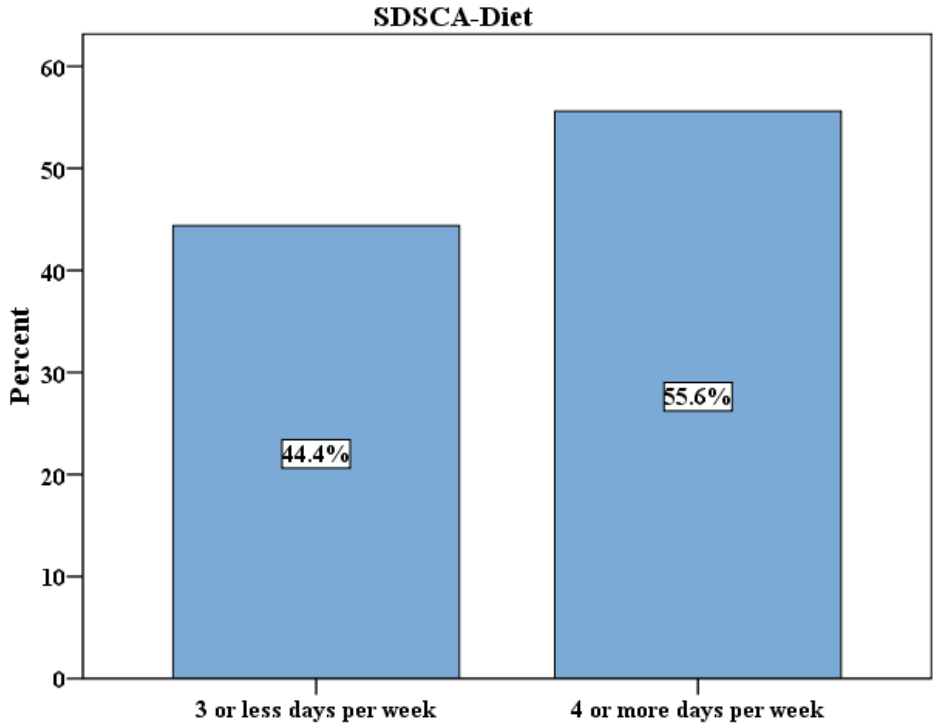
Lic. Beatriz Elena Meza Cuervo .
Translator and Interpreter

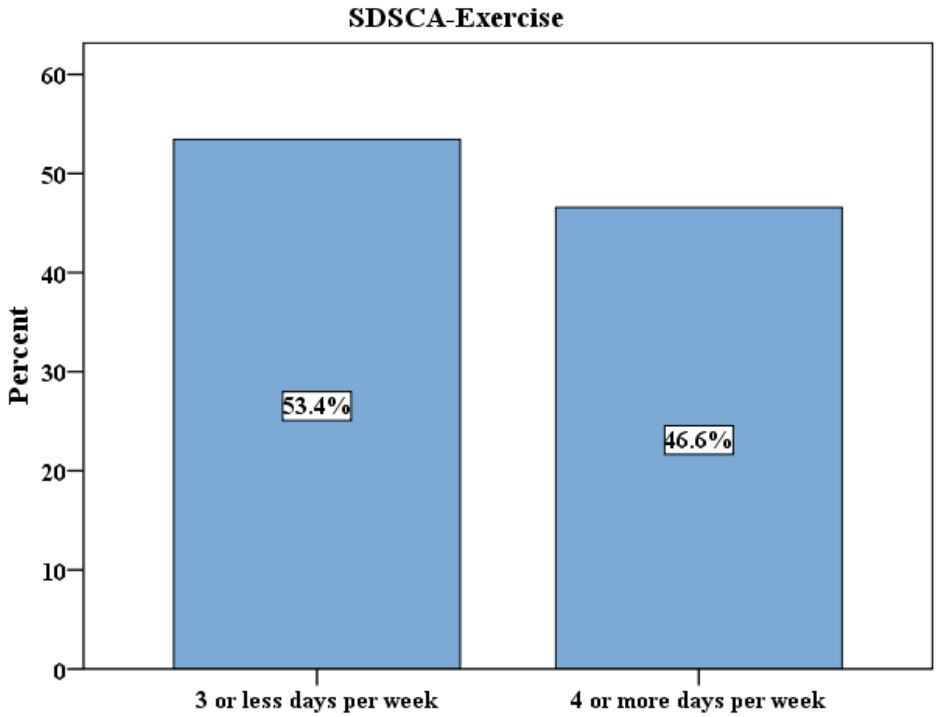
Wagner #313, Col. León Moderno
León, Guanajuato, C.P. 37480
Tels. (477) 636-0101 y 712-0266
peritostraductores@gmail.com

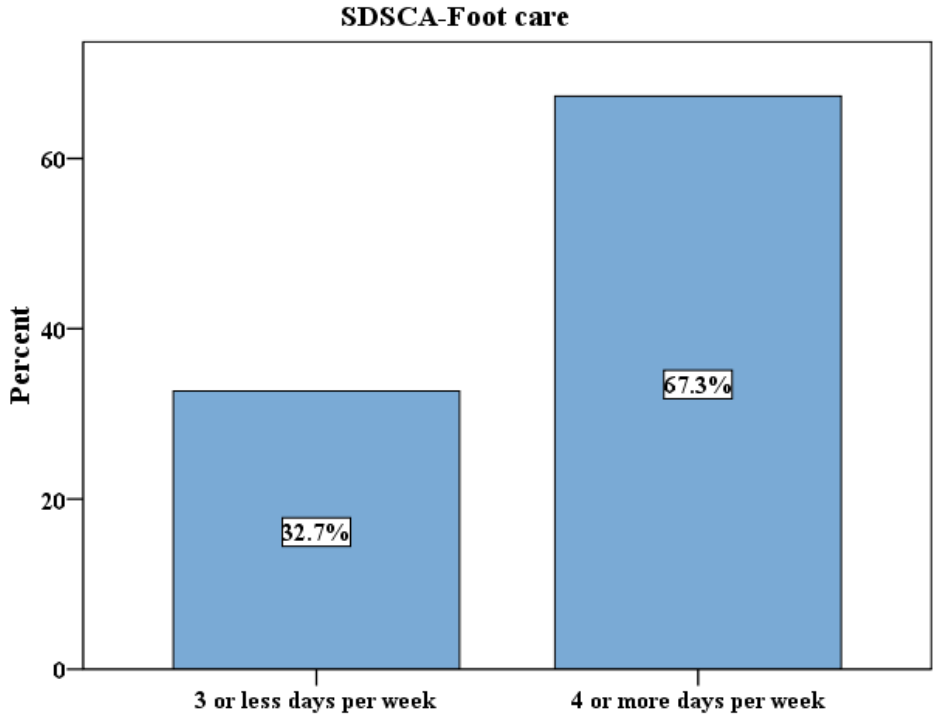
Appendix 9.1 **Histogram of Diabetes Knowledge Questionnaire frequency distribution**

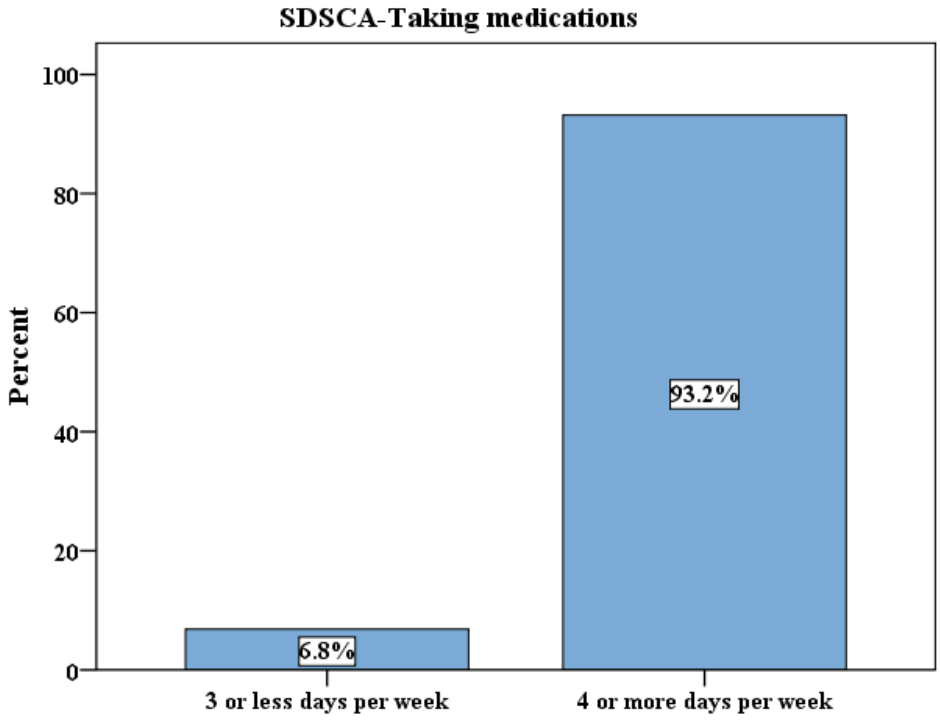


Appendix 9.2 **Bar charts of self-management behaviours included in the total score of the Summary of Diabetes Self-Care Activities**

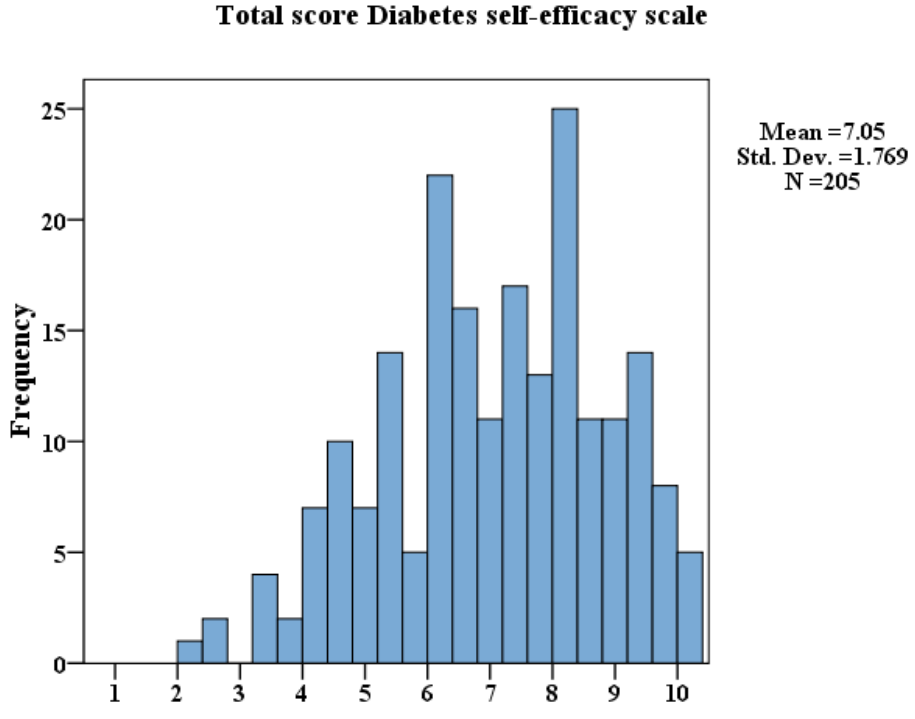



SDSCA-Exercise
Percent
60
50
40
30
20
10
0
53.4%
46.6%
3 or less days per week
4 or more days per week

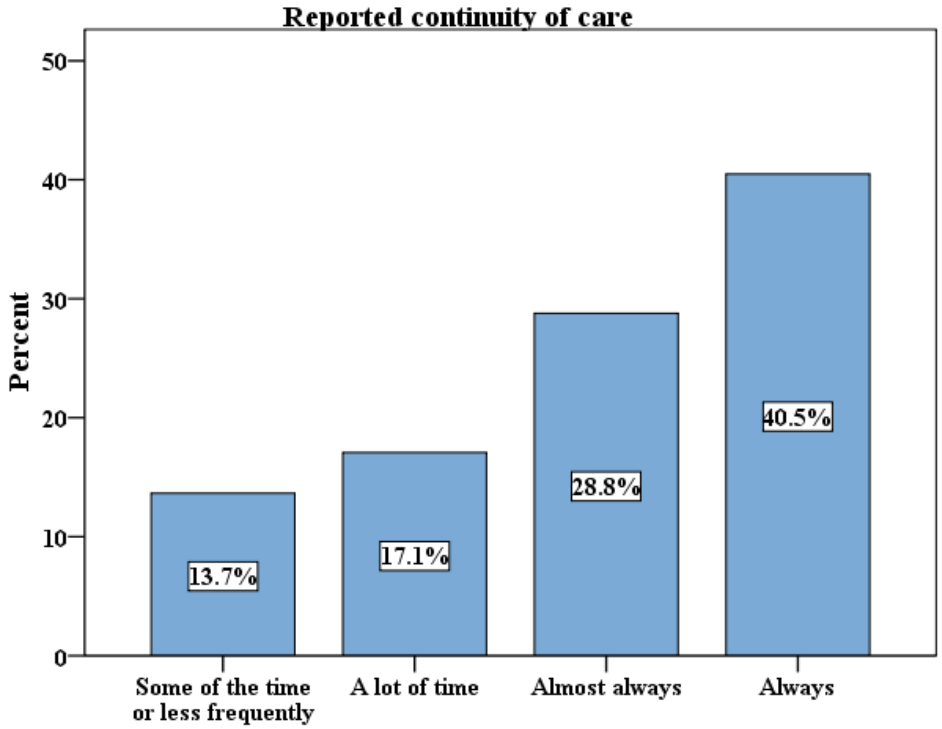

SDSCA-Foot care
Percent
60
40
20
0
32.7%
67.3%
3 or less days per week
4 or more days per week



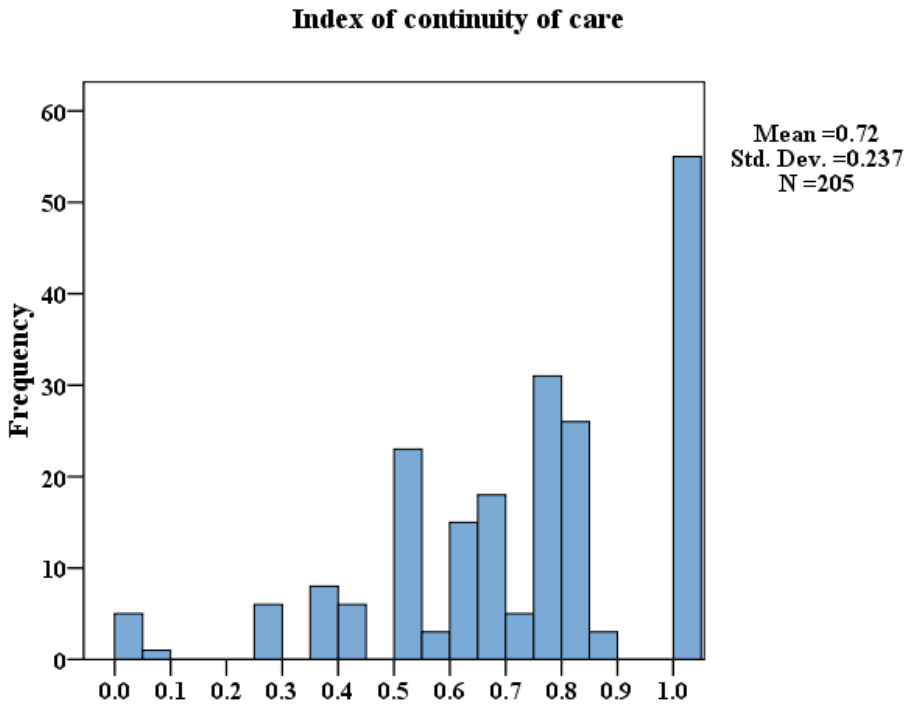
Appendix 9.3 Histogram of Diabetes self-efficacy scale frequency distribution



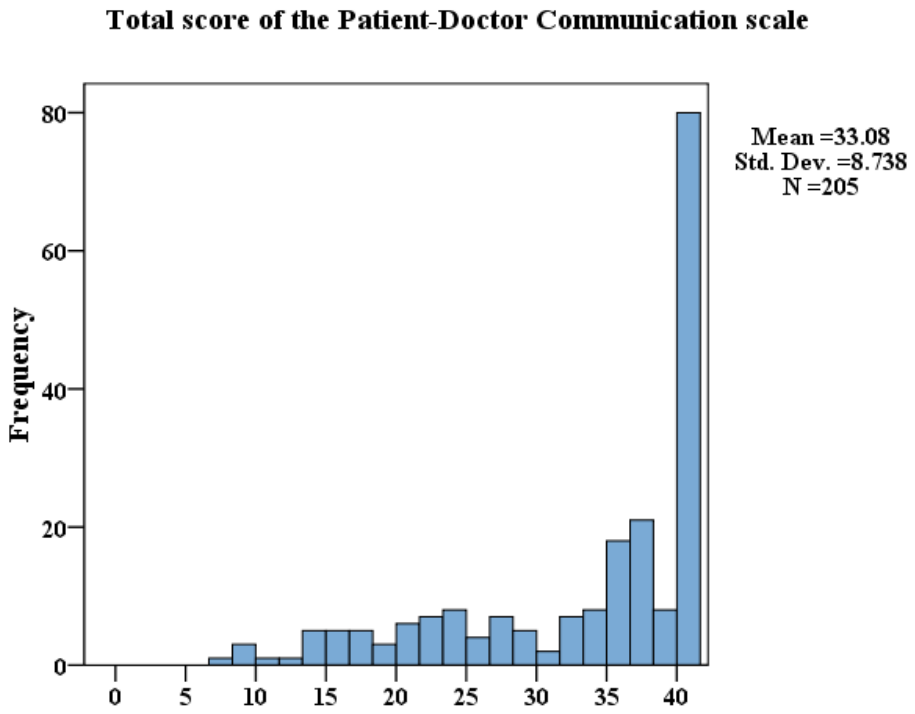
Appendix 9.4 Bar chart of frequencies in the reported continuity of care



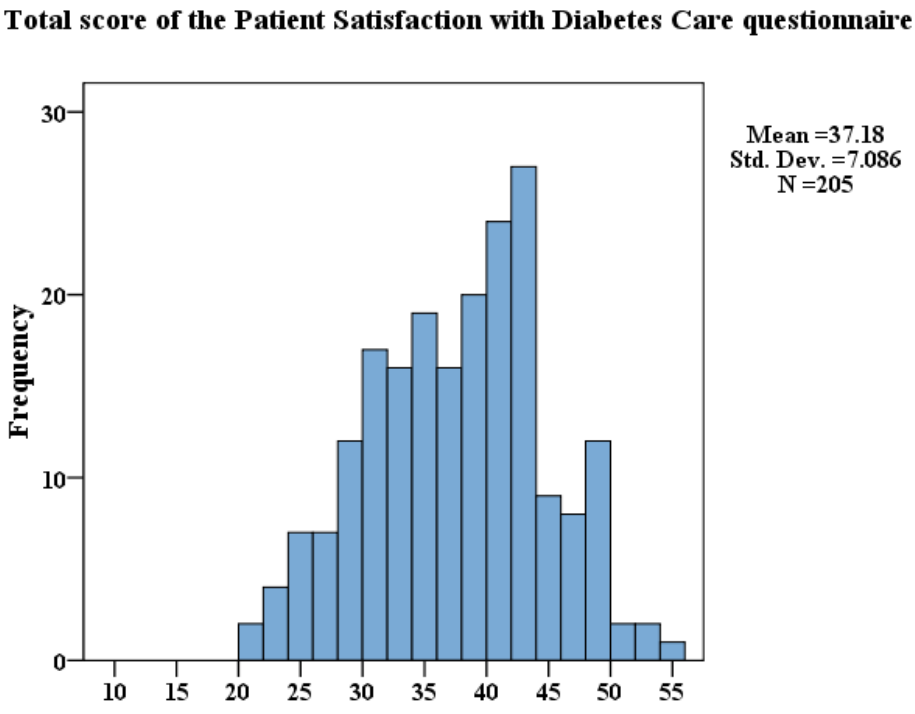
Appendix 9.5 Histogram of the index of continuity of care frequency distribution



Appendix 9.6 Histogram of the Patient-Doctor Communication Scale frequency distribution



Appendix 9.7 Histogram of the Patient Satisfaction with Diabetes Care questionnaire frequency distribution



Appendix 9.8 Change in HbA1c at follow-up as dependent variable

Linear regressions with change in HbA1c at follow-up as dependent variable

Factors	Univariate analysis		Multivariate analysis			
	Unstandardised coefficients (95% CI)	Beta	Unstandardised coefficients (95% CI)	Beta	Unstandardised coefficients (95% CI)	Beta
HbA1c at baseline	-0.44 (-0.55 to -0.33) †	-0.49†	-0.49 (-0.62 to -0.35) †	-0.54		
Practice						
N° 7	-0.24 (-1.05 to 0.56)	-0.04	0.14 (-0.63 to 0.91)	0.02	-0.07 (-0.95 to 0.81)	-0.01
N° 8	0.31 (-0.38 to 1.01)	0.07	0.23 (-0.43 to 0.90)	0.05	0.45 (-0.30 to 1.21)	0.10
N° 9	-0.65 (-1.64 to 0.34)	-0.09	-1.20 (-2.16 to -0.24) *	-0.17	-0.66 (-1.75 to 0.42) †	-0.09
N° 10	0.62 (-0.11 to 1.36)	0.13	0.48 (-0.24 to 1.21)	0.10	1.06 (0.24 to 1.88)	0.22
Sampling						
Random sampling	-0.44 (-1.21 to 0.33)	-0.07	-0.42 (-1.12 to 0.27)	-0.07	-0.45 (-1.25 to 0.34)	-0.08
Demographic						
Age	-0.004 (-0.02 to 0.02)	-0.02	-0.02 (-0.06 to 0.003)	-0.15	-0.03 (-0.06 to 0.005)	-0.17
Gender						
Female	-0.005 (-0.54 to 0.53)	-0.001	0.01 (-0.54 to 0.58)	0.004	-0.04 (-0.69 to 0.60)	-0.01
Marital status						
Without partner	-0.26 (-0.87 to 0.33)	-0.06	-0.19 (-0.77 to 0.39)	-0.04	0.08 (-0.6057 to 0.75)	0.02

Educational level						
Primary school	-0.19 (-0.83 to 0.45)	-0.04	-0.32 (-0.93 to 0.29)	-0.07	-0.13 (-0.83 to 0.56)	-0.03
Secondary school	-0.26 (-1.05 to 0.53)	-0.05	-0.23 (-1.04 to 0.56)	-0.04	-0.30 (-1.21 to 0.61)	-0.05
From technician to postgraduate	-0.54 (-1.31 to 0.22)	-0.10	-0.66 (-1.43 to 0.10)	-0.13	-0.67 (-1.55 to 0.20)	-0.13
Employment status						
Patients without a job	0.11 (-0.46 to 0.70)	0.02	-0.007 (-0.65 to 0.63)	-0.001	0.27 (-0.45 to 1.0)	0.06
Clinical						
Duration of diabetes	0.008 (-0.02 to 0.04)	0.03	0.04 (0.008 to 0.08)*	0.18	0.05 (0.005 to 0.09)*	0.19
Cholesterol	-0.006 (-0.01 to 0.0007)	-0.12	-0.001 (-0.008 to 0.005)	-0.02	-0.0076 (-0.01 to 0.0006)	-0.13
Body mass index						
Overweight	0.52 (-0.31 to 1.36)	0.13	0.42 (-0.33 to 1.19)	0.11	0.71 (-0.15 to 1.59)	0.18
Obesity	0.31 (-0.54 to 1.17)	0.08	0.57 (-0.25 to 1.39)	0.14	0.88 (-0.05 to 1.82)	0.22
Hypertension	-0.32 (-0.88 to 0.23)	-0.07	-0.14 (-0.69 to 0.41)	-0.03	-0.50 (-1.13 to 0.11)	-0.12
Comorbidities	-0.02 (-0.19 to 0.15)	-0.01	-0.12 (-0.29 to 0.04)	-0.09	-0.07 (-0.27 to 0.11)	-0.06
Complications	-0.19 (-0.62 to 0.24)	-0.06	-0.13 (-0.53 to 0.27)	-0.04	-0.20 (-0.67 to 0.26)	-0.06
Beck Depression Inventory						
Mild to moderate depression	-0.30 (-0.90 to 0.29)	-0.07	-0.03 (-0.61 to 0.54)	-0.009	-0.06 (-0.72 to 0.60)	-0.01
Moderate to severe depression	-0.07 (-0.92 to 0.76)	-0.01	0.36 (-0.48 to 1.21)	0.06	0.31 (-0.66 to 1.28)	0.05
Severe depression	0.05 (-0.93 to 1.04)	0.008	-0.001 (-0.96 to 0.96)	-0.0001	0.04 (-1.05 to 1.14)	0.006
Medical prescription						

Combination therapy	0.15 (-0.40 to 0.71)	0.03	0.68 (0.12 to 1.25)*	0.16	0.30 (-0.33 to 0.94) †	0.07
Self-management						
Diabetes knowledge	-0.02 (-0.09 to 0.04)	-0.04	-0.02 (-0.09 to 0.05)	-0.04	-0.02 (-0.10 to 0.06)	-0.04
Self-management behaviours						
¾ behaviours 4≥ days per week	-0.13 (-0.66 to 0.39)	-0.03	-0.12 (-0.66 to 0.40)	-0.03	-0.19 (-0.80 to 0.41)	-0.05
Diabetes self-efficacy	0.05 (-0.09 to 0.20)	0.05	0.04 (-0.10 to 0.20)	0.04	0.12 (-0.05 to 0.30)	0.11
Quality of care						
Self-reported continuity of care						
A lot of time	-0.27 (-1.21 to 0.67)	-0.05	-0.17 (-1.06 to 0.71)	-0.03	-0.13 (-1.15 to 0.89)	-0.02
Almost always	0.10 (-0.74 to 0.95)	0.02	0.07 (-0.71 to 0.87)	0.01	0.14 (-0.76 to 1.04)	0.03
Always	0.51 (-0.29 to 1.32)	0.13	0.14 (-0.66 to 0.95)	0.03	0.47 (-0.44 to 1.40)	0.12
Index of continuity of care	0.34 (-0.76 to 1.45)	0.04	0.34 (-0.73 to 1.42)	0.04	0.03 (-1.26 to 1.20)	-0.003
Treatment intensification						
Appropriate	0.55 (0.03 to 1.08)*	0.14*	0.11 (-0.41 to 0.64)	0.02	0.81 (0.24 to 1.39) †	0.21
Patient-doctor communication						
Total score = 40	0.36 (-0.17 to 0.89)	0.09	0.14 (-0.36 to 0.64)	0.03	0.24 (-0.33 to 0.82)	0.06
Adjusted Model R^2			0.26†		0.04	

* P-value<0.05, † P-value<0.01

Appendix 9.9 Dichotomised HbA1c at follow-up as dependent variable

Logistic regressions with <u>dichotomised</u> HbA1c at follow-up as dependent variable (0= poor glycaemic control, 1= good glycaemic control)

Factors	Univariate analysis		Multivariate analysis			
	ORs	95% CI	ORs	95% CI	ORs	95% CI
HbA1c at baseline	0.51†	0.39 to 0.67	0.51†	0.36 to 0.73		
Practice						
N° 7	0.34	0.11 to 1.02	0.23	0.04 to 1.13	0.22	0.05 to 0.91
N° 8	0.33	0.13 to 0.84	0.21	0.06 to 0.76	0.29	0.09 to 0.91
N° 9	1.48	0.50 to 4.33 *	1.49	0.31 to 7.18	2.41	0.58 to 9.98
N° 10	1.21	0.54 to 2.72	0.61	0.17 to 2.08	1.04	0.35 to 3.09
Sampling						
Random sampling	1.04	0.43 to 2.54	0.87	0.23 to 3.24	0.87	0.26 to 2.90
Demographic						
Age	0.99	0.96 to 1.02	0.93*	0.88 to 0.99	0.93*	0.88 to 0.99
Gender						
Female	0.75	0.40 to 1.39	0.56	0.20 to 1.57	0.59	0.22 to 1.52
Marital status						
Without partner	1.28	0.65 to 2.53	1.91	0.68 to 5.31	2.35	0.89 to 6.20
Educational level						

Primary school	1.04	0.48 to 2.22	0.95	0.31 to 2.89	1.21	0.42 to 3.43
Secondary school	1.61	0.66 to 3.94	2.16	0.52 to 8.95	1.97	0.54 to 7.12
From technician to postgraduate	1.24	0.51 to 3.03	0.93	0.22 to 3.86	1.03	0.28 to 3.78
Employment status						
Patients without a job	1.18	0.59 to 2.35	2.97	0.84 to 10.41	3.44*	1.13 to 10.45
Clinical						
Duration of diabetes	0.95*	0.90 to 0.99	0.98	0.91 to 1.05	0.98	0.92 to 1.03
Cholesterol	0.99	0.99 to 1.0	0.99	0.98 to 1.0	0.99	0.98 to 1.0
Body mass index						
Overweight	1.24	0.47 to 3.28	0.72	0.18 to 2.85	0.91	0.26 to 3.13
Obesity	0.82	0.30 to 2.27	0.62	0.14 to 2.75	0.94	0.24 to 3.61
Hypertension	0.72	0.38 to 1.36	1.33	0.51 to 3.45	1.05	0.43 to 2.53
Comorbidities	0.95	0.77 to 1.16	0.98	0.70 to 1.36	0.97	0.72 to 1.30
Complications	1.20	0.73 to 1.95	1.61	0.79 to 3.25	1.57	0.82 to 3.0
Beck Depression Inventory						
Mild to moderate depression	0.80	0.40 to 1.58	0.75	0.27 to 2.11	0.75	0.29 to 1.93
Moderate to severe depression	0.28	0.07 to 1.01	0.50	0.08 to 2.99	0.47	0.09 to 2.49
Severe depression	1.12	0.38 to 3.32	1.41	0.28 to 7.02	1.58	0.34 to 7.24
Medical prescription						
Combination therapy	0.22†	0.11 to 0.42	0.20†	0.07 to 0.55	0.14†	0.05 to 0.36

Self-management						
Diabetes knowledge	0.92	0.85 to 1.0	0.92	0.80 to 1.05	0.91	0.80 to 1.03
Self-management behaviours						
¾ behaviours 4≥ days per week	1.38	0.74 to 2.57	2.78*	1.06 to 7.30	2.70*	1.08 to 6.74
Diabetes self-efficacy	1.07	0.90 to 1.28	0.97	0.74 to 1.26	1.01	0.79 to 1.30
Quality of care						
Self-reported continuity of care						
A lot of time	0.82	0.28 to 2.36	2.49	0.49 to 12.65	1.72	0.39 to 7.59
Almost always	0.56	0.21 to 1.48	0.66	0.16 to 2.78	0.75	0.20 to 2.78
Always	0.73	0.29 to 1.81	0.87	0.21 to 3.62	1.10	0.29 to 4.06
Index of continuity of care	0.96	0.26 to 3.48	3.54	0.56 to 22.11	2.48	0.48 to 14.06
Treatment intensification						
Appropriate	2.54†	1.31 to 4.91	1.03	0.40 to 2.65	1.98	0.86 to 4.51
Patient-doctor communication						
Total score = 40	0.66	0.34 to 1.25	0.34*	0.13 to 0.86	0.43	0.18 to 1.02
R^2				0.34†		0.26†

ORs = Odds Ratios, CI = Confidence Intervals, BDI = Beck Depression Inventory, * P-value<0.05, † P-value<0.01

Appendix 10.1 Description of self-management interventions from reviews and meta-analysis (randomised controlled trials)

Review/meta-analysis	Study author and year	F/U in months	Self-management			Outcome	Quality of study
			Behaviours	Knowledge	Self-efficacy	Glycaemic control	
Norris 2001 Gary 2003 Sarkisian 2003	Mazzuca 1986 Vinicor 1987	14	✓	✓	-	✓	PB, AB, DB, MQ
Norris 2001	McCulloch 1983	6	-	✓	-	✓	DB
Norris 2001 Gary 2003	Scott 1984	1	-	✓	-	✓	AB, MQ
Norris 2001	Wise 1986	6	-	✓	-	✓	PB
Norris 2001 Deakin 2005	Heller 1988	12	-	✓	-	✓	HRB
Norris 2001	Anderson 1995	1.5	-	-	✓	✓	SB, PB
Deakin 2005	Lozano 1999	24	-	✓	-	✓	HRB
Deakin 2005	Trento 2001	24	-	✓	-	✓	HRB
Deakin 2005	Brown 2002	12	-	✓	-	✓	HRB
Deakin 2005	Trento 2002	48	-	✓	-	✓	HRB
Deakin 2005	Deakin 2003	14	-	✓	-	✓	MRB
Norris 2001 Sarkisian 2003	Falkenberg 1986	6	-	✓	-	✗	PB, AB, DB
Norris 2001 Gary 2003	Bloomgarden 1987	18	✗	✓	-	✗	DB, HQ
Norris 2001	de Weerdt 1989 de Weerdt 1991	6	✓	✓	-	✗	PB, DB
Norris 2001	Estey 1990	3	✓	-	-	✗	PB
Norris 2001 Sarkisian 2003	Gilden 1992	24	-	✓	-	✗	SB, PB
Norris 2001	Tu 1993	2	✓	-	-	✗	PB, DB

Review/meta-analysis	Study author and year	F/U in months	Self-management			Outcome	Quality of study
			Behaviours	Knowledge	Self-efficacy	Glycaemic control	
Norris 2001 Gary 2003	Arseneau 1994	5	-	✓	-	✗	SB, AB, LQ
Norris 2001 Gary 2003	Campbell 1996	6	-	✓	-	✗	SB, PB, AB, MQ
Norris 2001	Hawthorne 1997	6	✓	✓	-	✗	PB
Norris 2001	Mazzuca 1997	8	✓	✗	-	✗	AB, DB
Norris 2001 Deakin 2005	Trento 1998	12	-	✓	-	✗	PB, HRB
Norris 2001	Ridgeway 1999	6	-	✓	-	✗	PB, AB
Norris 2001	Raz 1988	12	-	✗	-	✓	PB
Norris 2001 Gary 2003	D'Eramo-Melkus 1992	6	-	✗	-	✓	SB, PB, AB, HQ
Norris 2001	Lo 1996	3	-	✗	-	✓	NPR
Norris 2001 Gary 2003 Sarkisian 2003	Agurs-Collins 1997	6	-	✗	-	✓	PB, AB, HQ
Deakin 2005	Rickheim 2002	6	✗	✗	-	✓	HRB
Norris 2001	White 1986	6	-	✗	-	✗	AB
Norris 2001	Kruger 1992	6	✗	✗	-	✗	AB, DB
Sarkisian 2003	Corkery 1997	7.7	✗	✗	-	✗	AB
Norris 2001	Kaplan 1985 Hartwell 1986 Kaplan 1987	18	-	-	-	✓	SB
Gary 2003	Greenfield 1988	3	-	-	-	✓	HQ
Gary 2003	Morgan 1988	2	-	-	-	✓	MQ
Gary 2003	Weinberger 1995	12	-	-	-	✓	HQ
Sarkisian 2003	Jaber 1996	4	-	-	-	✓	NPR

Review/meta-analysis	Study author and year	F/U in months	Self-management			Outcome	Quality of study
			Behaviours	Knowledge	Self-efficacy	Glycaemic control	
Norris 2001 Sarkisian 2003	Brown 1999	12	-	-	-	✓	PB, AB, DB
Deakin 2005	Zapotoczky 2001	12	-	-	-	✓	MRB
Norris 2001	de Bont 1981	6	-	-	-	✗	NPR
Norris 2001	Wing 1985	16	-	-	-	✗	SB, PB
Norris 2001 Gary 2003	Wing 1986	12	-	-	-	✗	SB, LQ
Norris 2001	Heitzman 1987	18	-	-	-	✗	NPR
Norris 2001	Korhonen 1987	12	-	-	-	✗	NPR
Norris 2001	Mulrow1987	11	-	-	-	✗	PB, AB
Norris 2001	Pratt 1987 Wilson 1987	4	-	-	-	✗	SB, PB
Norris 2001	Wing 1988	12	-	-	-	✗	SB, DB
Gary 2003	Wing 1988	15.5	-	-	-	✗	MQ
Norris 2001	Glasgow 1989	2	-	-	-	✗	PB, AB, DB
Gary 2003	Morrish 1989	6	-	-	-	✗	LQ
Gary 2003	Rost 1991	4	-	-	-	✗	MQ
Norris 2001 Gary 2003 Sarkisian 2003	Glasgow 1992	6	-	-	-	✗	SB, PB, MQ
Norris 2001	Vanninen 1992 Laitinen 1993 Uusitupa 1993 Uusitupa 1996	27	-	-	-	✗	PB, DB
Norris 2001	Boehm 1993	Unclear	-	-	-	✗	SB
Gary 2003	Hurwitz 1993	24	-	-	-	✗	MQ
Norris 2001	Franz 1995	6	-	-	-	✗	SB, PB, AB

Review/meta-analysis	Study author and year	F/U in months	Self-management			Outcome	Quality of study
			Behaviours	Knowledge	Self-efficacy	Glycaemic control	
	Franz 1995						
Norris 2001	Glasgow 1995 Glasgow 1996 Glasgow 1997	12	-	-	-	✗	NPR
Gary 2003	Aikens 1997	2	-	-	-	✗	LQ
Gary 2003	Ligtenberg 1997	6.5	-	-	-	✗	MQ
Norris 2001	Perry 1997	6	-	-	-	✗	SB, PB, DB
Sarkisian 2003	Noel 1998	6	-	-	-	✗	NG
Norris 2001	Mengham 1999	12	-	-	-	✗	NPR
Deakin 2005	Holtrop 2002	6	-	-	-	✗	HRB

F/U = follow-up, ✓ = improvement, ✗ = no improvement, - = it was not an outcome in the study, SB = selection bias [Norris 2001], PB = performance bias [Norris 2001], AB = attrition bias [Norris 2001], DB = detection bias [Norris 2001], LQ = low quality [Gary 2003], MQ = moderate quality [Gary 2003], HQ = high quality [Gary 2003], LRB = low risk of bias [Deakin 2005], MRB = moderate risk of bias [Deakin 2005], HRB = high risk of bias [Deakin 2005], NPR = no problems reported, NG = not given.

Appendix 10.1 shows 62 RCTs extracted from the reviews. A tick (✓) is included in studies that reported an effect of the intervention compared with control group. The lack of effects of intervention is represented with a cross (✗). A hyphen indicates that studies did not report the effect of the intervention on self-management. The last column shows the quality of every study provided by the reviews. In the last column, there might be more than one evaluation either from the same review or from more than one review. For example the study by Mazzuca (1986) and Vinnicor (1987) was evaluated with performance bias, attrition bias, and detection bias by Norris (2001). Gary (2003) classified the same study as moderate quality. Sarkisian (2003) did not provide a specific evaluation for every included study in their review.