The role of PROMs in modern healthcare: challenges and strenghts

---

A systematic literature review

Master thesis

Business Administration and Innovation in Health Care

Author: Domenico Longo (124215)

Supervisor: Pedro Oliveira

Correlator: Maria Helena Mouriño Silva Nunes

Hand-in date: 15/01/2021

ABSTRACT

Background: The academic and scientific research agrees in saying that Patient Reported Outcomes (PROMs) are valid tools, to both assess (and even improve) quality of life and self-awareness of the patients and to enhance patient-clinician communication. Despite that, the adoption of PROMs in routine care meets limitations and entrance barriers. Today the main use of PROMs rests in Random Clinical Trials and in other types of studies. With poor use in routine care.

Objectives: The main purpose of the study is to present a research overview and an agenda for researchers. Secondly it tries to explain the limited use of Patient Reported Outcomes in routine clinical care.

Methods: The paper is a systematic literature review and it follows the PRISMA model for Meta-analyses and systematic reviews. The main source of the the literature will be focused mostly on secondary data. The data were collecting in peer-reviewed journal, with a precise methodology.

Originality/Value: The paper inspects the actual status of the use of PROMS in diabetes. The literature has a number of studies and reviews about the topic, however they do not inspect the same side of the problem.

Articolo I. Sommario

List of acronyms

PROMs: patient reported outcome measures

EQ-5D: Euroqolol 5-dimensions

SF-36: Short Form – 36

1. Introduction

1.1 Value and patient-centered care

Over the last 10 years, “value” received an higher attention in health care sector. It gained an increasing importance in the decisions, strategies and even in the delivery of Health Care. In 2010, the Harvard economist Michael Porter, started to talk about “value based health-care” as a new framework for health care. What this new framework aims to achieve is to place the patient outcomes at the centre of the health care model; to quote Porter: “Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent”.

The main focus of the work of Porter and value based health care is to detect where the value lies and to find the best (and efficient) ways to assess the value itself. This is not an easy challenge, as it requires a change not only in the processes but in the mindset as well. One of the main concern of Porter is to highlight that value doesn’t depends on the volume of service delivered, rather it does on outcomes relative to costs. That being said, it is crucial to understand that value based health care, does not seek for costs reduction without any regard to outcomes; value based health care instead, aims to deliver a more efficient care delivery and to avoid any useless or not essential service (volume is not the key to gain outcomes). (Porter, 2010)

The patient, plays a main role in this model: In the last years, within the health care environment, the term “patient-centered” is becoming more and more crucial, as in this view, the patient must be involved in the process of care, in the important decisions towards his or her clinical situation. And beyond the patients, of course, their families and relatives.

One of the best possible example of patient centered-care is provided by PROMs, through which, the patient can play an active role in the process of care.

1.2 PROMs: a resource in patient-centered care

In general, the acronym PROMs (Patient Reported Outcomes Measures) groups a series of tools that aim to evaluate the general quality of life of an individual. Reported outcomes are instruments like questionnaires and surveys, filled but no one that the patient its/herself, withouth any help or influence from any of the health care staff or clinicians. The peculiarity of these questionnaires are that they are all standardized, which makes it possible to prform a comparison between or within interventions, or to "scale" the results and to have a deeper analysis of the outcomes/data.

The roles of such instruments are multiple:

In the first place, they provide an overview of the health related quality of life (HRQOL) of the patient, by giving question about pain, symptoms, physical and mental well-being. The analysis of this type of questionnaire focuses on different "dimensions" as it will be described further in the paper.

Secondly, one of the main role of PROMs is the comparison of outcomes. Giving their standardized nature, in fact, it is possible to compare the outcomes overtime, to assess whether or not a patient is improving in his/her recovering, of his/her health related quality of life perception changed during a certain period. But this is just a side of the their usage.

Through the standardized outcomes, it is possible to think on a larger scale, by comparing the behaviour of patients from different area in regard to a certain pathology, to compare the effectiveness of treatment, and finally, to compare the results of different health care systems.

The area of application of PROMs is manifold, as manifold is their nature. The aim of this paper is to present the charcteristics of PROMs and their appilication in health care, with particular attention to the type 2 diabetes pathology.

1.3 Rationale of the research

The topic of Patients Reported Outcomes was addressed by the author of this thesis during the academical experience at Copenhagen Business School. The two years of the Master degree, outlined the importance of the patient perspective, not only from a clinical point of view, but also from a health economic planning point of view.

Before the selection of the main literature for this thesis, a research was carried out by the student, mainly guided by pure curiosity and by the ideas captured by the professors and by the subjects studied. The result of this research was the input that led to the creation of this thesis. The main observation was that the revolutionary and patient-centered aspect of PROMs was broadly recognized by the literature and by stakeholders, both with health and economical background (ICHOM - International Consortium for Health Outcomes Measurement). However, this statement come with some criticism, In fact, the positive and innovative role of PROMs has not always found confirmation in literature and in real life cases.

The use of such tools hides several challenges and issues despite having been created and evolved as a support tool for both the patient and those who take care of him.

With this concept in mind, this thesis aims to understand the reason and challenges that lie behind the full implementation and adoption of PROMs worlwide.

1.4 Research Questions

“Much of clinical care is directed at making patients ‘‘feel better,’’ but patients’ reports on their functioning and wellbeing have only rarely been collected in a standardized fashion in routine clinical practice.” (Snyder C.)

With the purpose of deepening this topic, the target of this thesis will be to answer to these question

“Why the use of PROMs remains mostly confined to clinical trials and does not seem to be able to spread into clinical routine practices worldwide?”

Sub-Questions

- “What are patients and health care professional opinion and experiences about the use of PROMs?”
- “Which challenges do the adopters of PROMs need to overcome?”

2. Literature Background

During the literature research for the thesis, a substantial number of reviews and studies have been found on the topic of PROMs. The idea behind this chapter is to present a brief but comprehensive overview of the main findings in the academic and scientific environment. However, the field of the research is vaste and multi-dimensional

This section has the goal to present to the reader the topic of PROMs, in order to give a base understanding of the topic. The different types of PROMs will be presented and discussed; the reader will get the idea behind these tools and the importance of measuring the heaalth related quality of life, as it emerges from the literature.

2.1 Patient Reported Outcomes in the academic literature

In the perspective of patient centered care, PROMs are certainly some of the most representative instruments, in fact, the collection of data relies completely on the patient, who plays a more important role in its disease management.

The acronym PROMs, stays for Patient Reported Outcomes Measures; according to the definition from FDA, PROMs are: "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (U.S. Food and Drug Administration).

The first measures of reported outcomes were used during the seventies as an assessement of the level of pain from the patients. These tools evolved through the years and they increased their importance in the treatment of diseases. They were adopted mostly in clinical trials to assess whether a treatment was effective or not. (Atherton PJ, Sloan JA., 2006 – 2007)

In the past, the use of PROMs was marginal and limited to clinical trials and studies, but during the years, it gained more importance and the role of reported outcomes changed. Today, in fact, PROMs have two main function: in their first function, PROMs are used by clinicians to enhance the clinical management of individual patient, while their second function is the comparison of the outcomes achieved by healthcare providers. However, the topic of PROMs and their use in the clinical treatment of diseases is still object of studies from the academic community. (Snyder CF et al.)

The Involvement of patients in the disease treatment has changed from simply seeking people's satisfaction with their care. What PROMs want to do is to inspect patients' views of symptoms, functional status, and their health related quality of life. Even though PROMs are outcomes measure, their main use is to measure health, in fact, by comparing the patients' results overtime, it is possible to measure the overall quality of the care received. (Black, 2013)

Data gathered from PROMs allow to integrate the outcomes from the patients (patient perception of its health situation) with the data producted by clinicians and health professionals. The final goal of the integration is to understand whether a treatment made a real and effective difference for the patient by improving his/her health and quality of life.

During the first decade of 2000s, proof of the increasing role of PROMs can be found in the action of several health care systems in europe: In the United Kingdom, for instance, different policies encouraged a wider use of patient reported outcomes, in order to strenghten patient-clinician communicaton and to provide a better evaluation of the national health system. (Evans J.P., 2018)

While in the United Kingdom, PROMs cover mostly a comparative and evaluative role, in Scandinavian countries -especially in Sweden- and in the USA, their application was more "clinical-driven", in fact, for the most part, they were applied by the clinicians and health care professionalities principally to improve clinical and individual care of the patient. (Black, 2013 – Snyder, 2015)

There are thousands of PROMs and new ones are created every day. Numerous primary care interventions have been developed in recent years to encounter changing population needs, like people with several morbidity or aging population for instance.

PROMs can be divided in two groups: generic and disease specific. The difference between the two types stays their use and in the outcomes they want to achieve. Generic PROMs, cover multi-dimensional field encompassing aspects of enablement, resilience, symptoms and function, and health perceptions, defining, in essence, the perceived health related quality of life of a patient at a certain time (and comparing with the previous situation). The disease-specific PROMs aim to inspect a specific issue or problem for the patient regarding a certain disease or condition. Disease specific measures are more tailored and they have a precise goal, they go more into details rather than offer an overall assessment like the generic one. Every disease specific PROM changes deeply depending on the disease it is assessing. (Murphy M. et al, 2018)

However, it is fairly common to see generic and disease-specific PROMs being used togheter, exploiting the combined action of the first who allows comparison during time and the second one who gives more specific and disease or condition-related data. (Weldring T. and Smith S., 2013)

2.2 Health Related Quality Of Life and generic PROMs

The health related quality of life (HRQOL from now) of an individual patient, is the major output of the generic PROMs. The term HRQOL is often confused with "health status" and "quality of life" in the literature. Even though sometimes in the literature these terms overlap with each other (Karimi M – Brazier J. 2016), the most widespread and prefarable opinion (as noted in the literature) sees HRQOL as the explanation of "how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health", with functioning representing the ability of an individual to perform daily activities and wellbeing including the individual subjective feelings. (Hays RD, Reeve BB, 2010)

The importance of HRQOL is well established in the literature, many authors agree in saying that evaluate the HRQOL of an individual is useful to assess the impact of a cronic condition on him/her. Another reason to measure HRQL is to study the different responses that patient with same clinical criteria. For example, two patients with the same range of motion and even similar ratings of back pain may have different role function and emotional wellbeing. Even if some individual may continue to carry their lives normally (going to work and other ruotine actions) without major depression, others may quit their jobs and have major depression. (Gordon H. et al) The effects of medical and clinical interventions on HRQOL are the kind of information that are the most interesting to all the stakeholders interested (not only clinician but patients a well).

Furthermore in the last decades an increasing efforts exist to incorporate HRQLs as measures of the quality of care and of clinical effectiveness, and payers are beginning to use HRQL information in reimbursement decisions and this is another reason why the measure of HRQOL is really important. (Porter, 2010)

The output of any generic PROMs must be standardised; the final result of an outcome measure translates qualitative questions, items and contents, into numbers. This happens for benchmarking reason but also to facilitate the reading of the questionnaire and to use the data to drive any medical decision. As already said, two of the main role of PROMs are: firstly, to check the actual HQOL of a patient and comparing it over time, secondly, to compare and evaluate the efficacy and effectiveness of the health providers on an aggregate level. (Euroqol group webpage)

It is possible to find a consistent variety of generic PROMs in the literature and many are created and developed every year. However, to be recognized and therefore applied by professionals, they need to be tested, not only to assess their validity as a tool, but to standardize them and make their outputs consistent with the parameters of health systems. In synthesis, their outputs must be “unanimously translatable”. An example of this is what the United Kingdom government made with PROMIS (Patient Reported Outcomes Measures Informartion System). PROMIS is a checklist of characteristics and guideline that any PROMS should have and follow to be reliable, valid to be applied inside the UK. All the outcomes must be measurable and PROMS must represent a tool for benchmarking healthcare performances. (Evans et al., 2018)

What follows is a presentation of some of different example of generic PROMs. The choice was made among the most recognized and used PROMs in the literature used in this thesis. The questionnaires examined are recognized and used globally in several countries from all over the world. (McKenna et al., 2011)

2.3 The EQ-5D-3L

"EQ-5D is a standardised measure of health status developed by EuroQol Group to provide a simple, generic measure of health for clinical and economical appraisal" (EQ-5D user guide)

The EQ-5D (Euroqol- 5 Dimension) is one of the most known and used generic patient reported outcome measures. The questionnaire is used in clinical trials, population studies and in routine clinical settings. It has been developed by the Euroqol Group, a not-for-profit organization formed by a network of experts in several academic disciplines. Euroqol Group is based in The Netherlands and its primary goal and investments is focused on the EQ-5D research. Euroqol was established in 1987 and at the beginning of its life it included european researchers. Today it has more than 90 members from Europe, North America, South America, Asia and Oceania. (Euroqol Group)

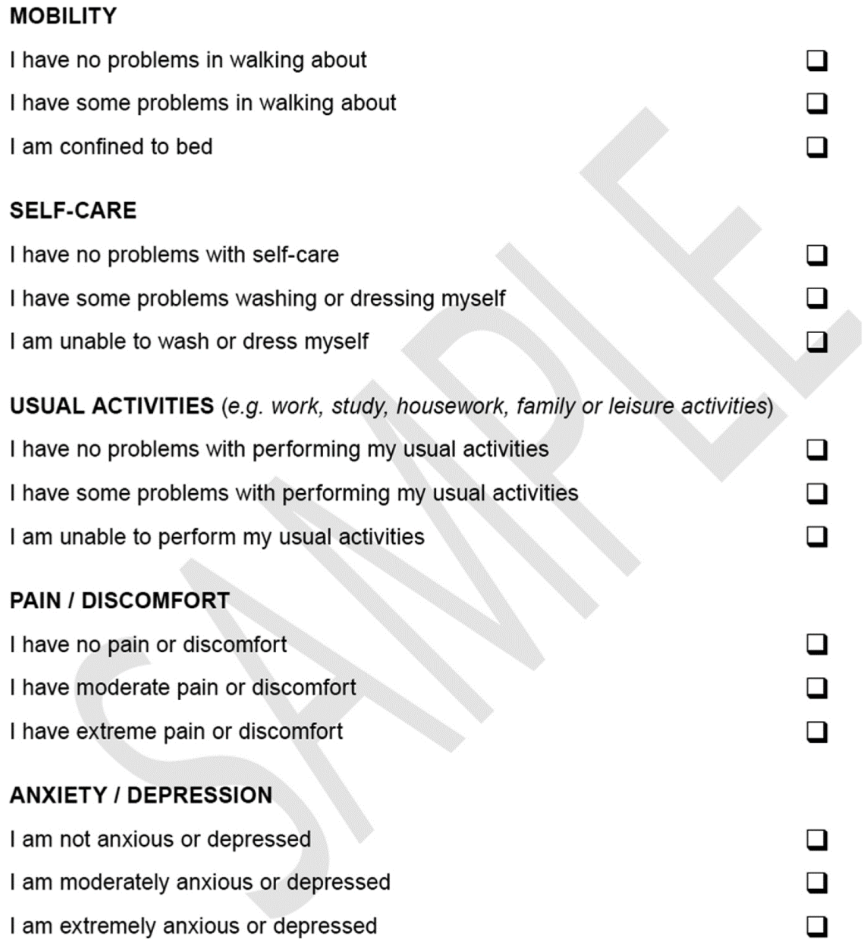
There are three versions of the EQ-5D: the most used one is the EQ-5D-3L, which is was the first version as well. A second version named EQ-5D-5L. The "L" stays for Levels; in fact, these tools measure respectively 3 and 5 severity levels, in 5 Dimensions, further explanations will be given in this paragraph. The last version of the questionnaire is the EQ-5D-Y, which is a simplified version for the youngest patient. Each of the version has been translated into the major languages, the process of translation must be validated through a close monitored process. The questionnaire is available in a paper version, digital version and it can be used online or via postal survey. Lastly, it is possible to perform the questionnaire in person by interviewing

the patient. The main feature of these questionnaires is that they are easy to fill, making them easy to use in all the circustances (clinical trial, routine measures and population studies). The Euroqol website presents a list of recognized studies who confirmed their reliability, responsiveness. It is possible to read these studies on the website, some of them have been included in the background literature of these thesis.

In each of its version, the EQ-5D consists of two elements in two pages: the first one is the EQ-5D descriptive system and the latter is the EQ-Visual analogue Scale (EQ-5D VAS).

The descriptive system includes the 5 dimensions of the assessment: Mobility, self-Care, Usual Activities, Pain/Discomfort and Anxiety/Depression.

Figure 1. Here is a sample of the Descriptive System of EQ-5D-3L, downloaded from the EQ-5D website.



MOBILITY

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

SELF-CARE

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

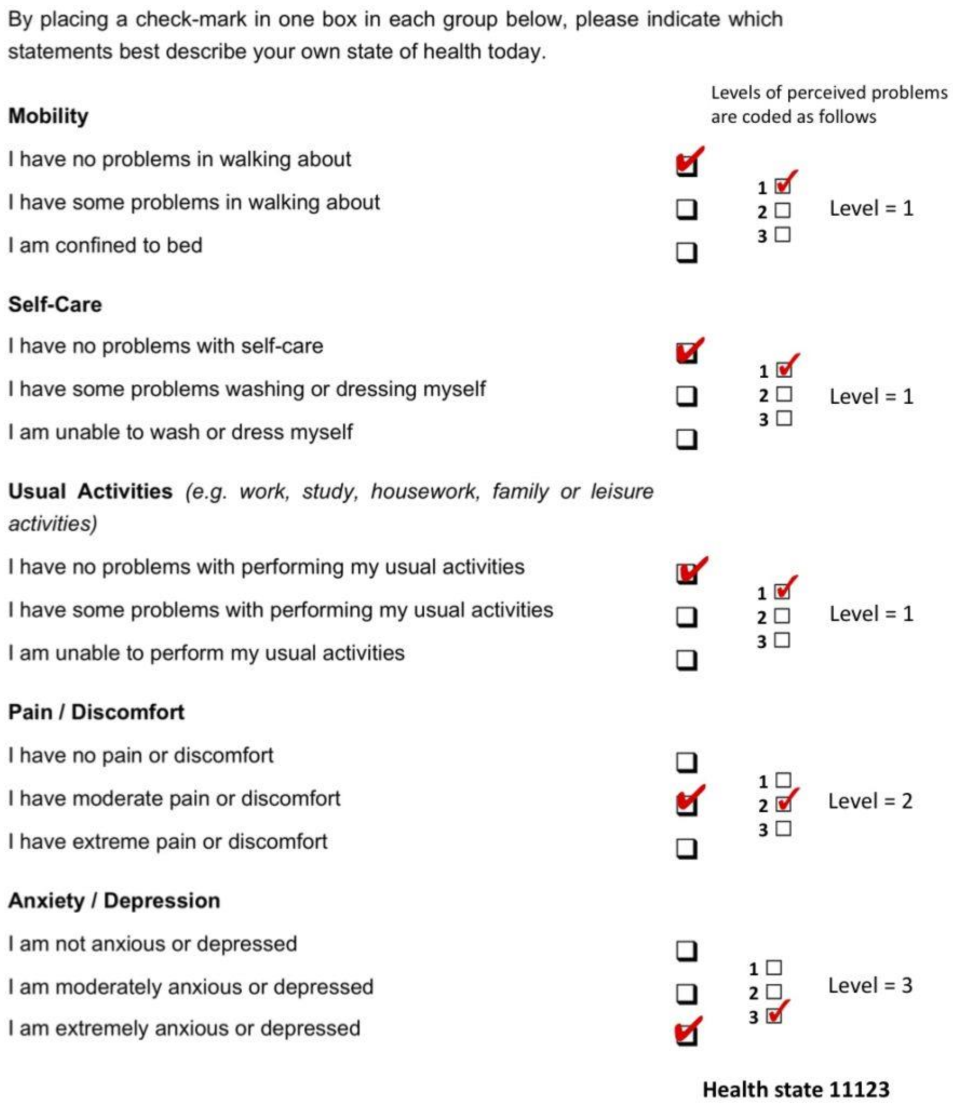
I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

Figure 1 shows the descriptive system of a EQ-5D-3L questionnaire, the respondent is asked to check the box that better describes his condition. From the highest to the lowest, the levels describe the severity of the dimension: with level 1 being “no problems”, level 2 “some problems” and level 3 “extreme problems”.

Figure 2. Here is a sample of a filled descriptive system of a EQ-5D-3L.



By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today.

Levels of perceived problems are coded as follows

Mobility

I have no problems in walking about ☑
I have some problems in walking about ☐
I am confined to bed ☐

1 ☑
2 ☐
3 ☐
Level = 1

Self-Care

I have no problems with self-care ☑
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

1 ☑
2 ☐
3 ☐
Level = 1

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☑
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

1 ☑
2 ☐
3 ☐
Level = 1

Pain / Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☑
I have extreme pain or discomfort ☐

1 ☐
2 ☑
3 ☐
Level = 2

Anxiety / Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☑

1 ☐
2 ☐
3 ☑
Level = 3

Health state 11123

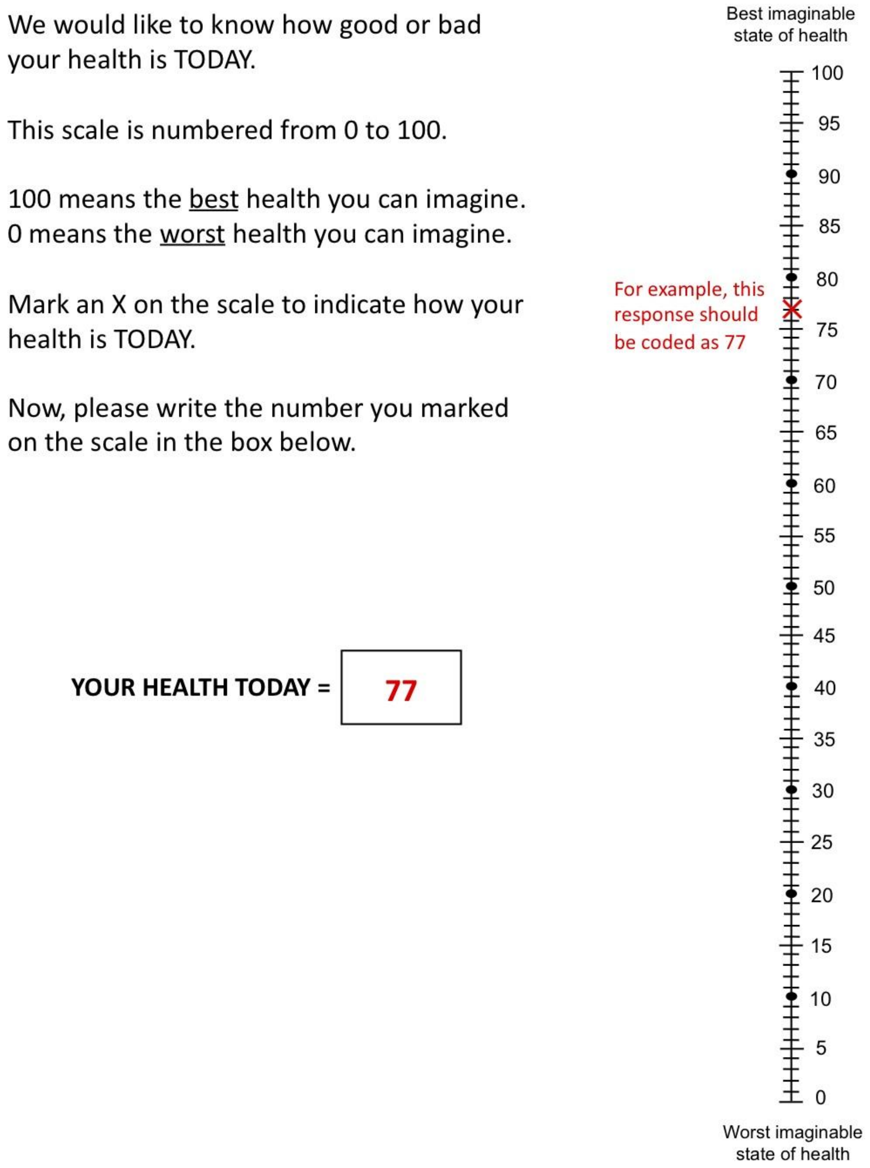
A first result of the descriptive system is the health state of the respondent. The health state is a 5-digit number that includes the combined levels of each dimension. In the example of figure 2, the health state of the respondent is 11123, meaning that checked level 1(no problems) for the first three dimensions, level 2 (moderate problems) for dimension 4 (Pain/Discomfort) and level 3 (severe problems) for the fifth dimension

(Anxiety/depression). There is a combination of 243 possible health states, where the better situation for a patient, would be a health state of 11111, meaning that he/she has no problems in any of the dimensions.

The health state has no arithmetic properties and it is not used to derive a summary score; in fact, this happens in a later step that follow a specific coding framework. (Euroqol and EQ-5D user guide)

The second item of the EQ-5D-3L (its content does not differ in the EQ-5D-5L) is the EQ-5D VAS.

Figure 3. A filled EQ- VAS example.



We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the <u>best</u> health you can imagine.
0 means the <u>worst</u> health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = 77

For example, this response should be coded as 77

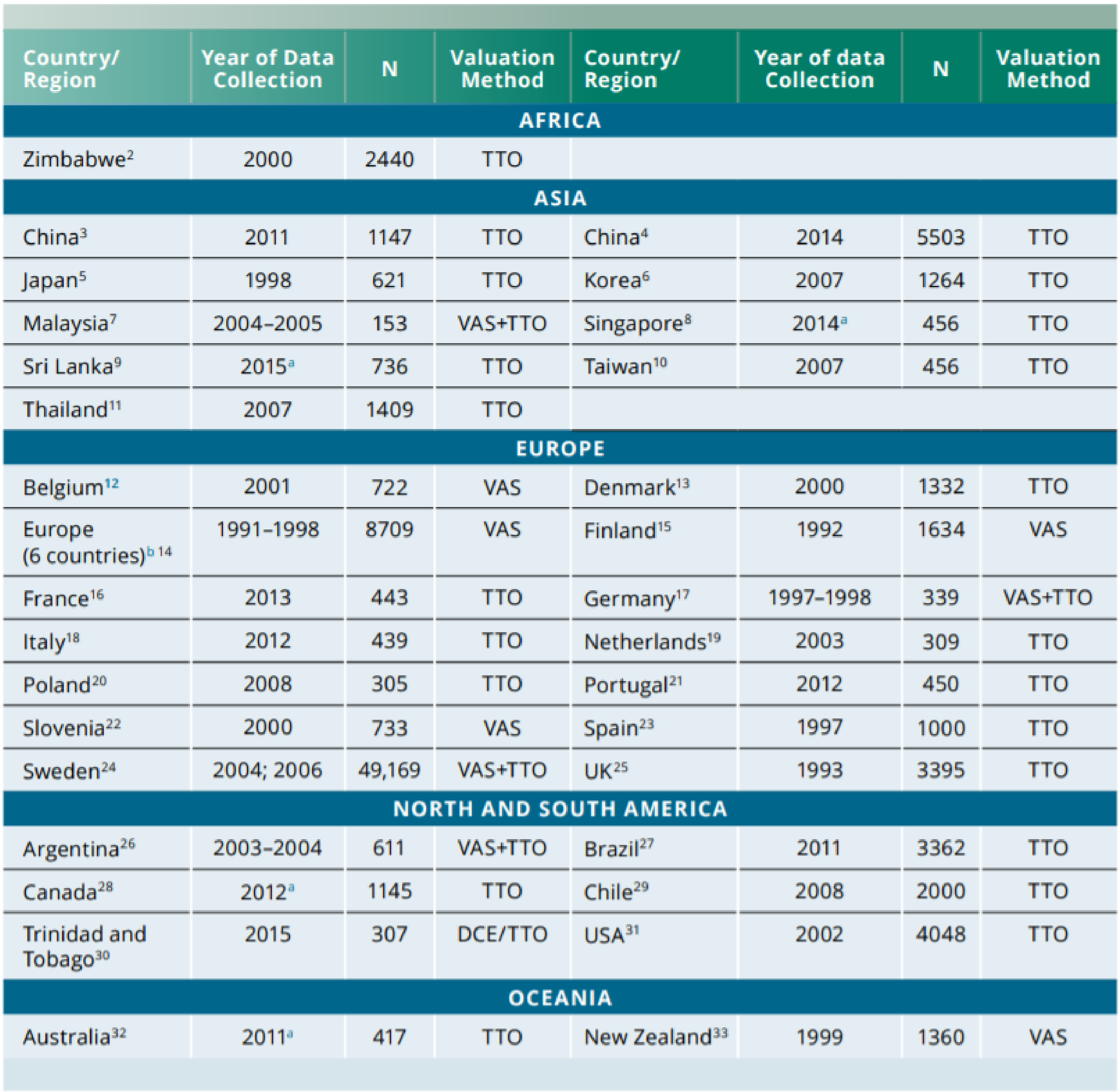
The EQ-5D Visual Analog Scale provides a self-rated quantitative measure of the patients' health outcome. Figure 2 shows an example of a patient who self-rated his/her health in the scale 77 out of 100, where 100 is the best health the patient can imagine.

With the completion of the VAS, the content of the questionnaire is finished and in the next phase, the results of the questionnaire (the 5-digit representing the health state and the VAS value) are translated into comparative data, the final output of the questionnaire. This information will be presented and used to possibly influence the decision-making process both at an individual level in the treatment of the patient, and at an aggregate health and economical level. (Devlin, 2010)

Firstly, a summary number, is taken from the health state of the questionnaire. This value explains how good or bad is the health state, if compared with the general population of a country/region. (Euroqol Group)

The summary number is derived by using a formula that attaches values (the Euroqol Group use the term “weights”) to the level of each dimension. The output is calculated by deducting the appropriate weight in a hypothetic scale from 0 to 1, where 0 stays for “death”, the worst scenario, and 1 stays for “full health”. (EQ-5D user guide)

As the summary number expresses a state health compared to the population of a country, these weights will be different, depending on the country they are calculated. The collection of this index values is called “value sets” and every country derives its index values using methods such the TTO (time trade-off). The Euroqol keeps track of every evaluation method for each country and an updated version is available for consultation on their website. Up to date, these are the value sets which are available on the Euroqol website.



Country/ Region	Year of Data Collection	N	Valuation Method	Country/ Region	Year of data Collection	N	Valuation Method
AFRICA							
Zimbabwe[2]	2000	2440	TTO				
ASIA							
China[3]	2011	1147	TTO	China[4]	2014	5503	TTO
Japan[5]	1998	621	TTO	Korea[6]	2007	1264	TTO
Malaysia[7]	2004–2005	153	VAS+TTO	Singapore[8]	2014[a]	456	TTO
Sri Lanka[9]	2015[a]	736	TTO	Taiwan[10]	2007	456	TTO
Thailand[11]	2007	1409	TTO				
EUROPE							
Belgium[12]	2001	722	VAS	Denmark[13]	2000	1332	TTO
Europe (6 countries)[b][14]	1991–1998	8709	VAS	Finland[15]	1992	1634	VAS
France[16]	2013	443	TTO	Germany[17]	1997–1998	339	VAS+TTO
Italy[18]	2012	439	TTO	Netherlands[19]	2003	309	TTO
Poland[20]	2008	305	TTO	Portugal[21]	2012	450	TTO
Slovenia[22]	2000	733	VAS	Spain[23]	1997	1000	TTO
Sweden[24]	2004; 2006	49,169	VAS+TTO	UK[25]	1993	3395	TTO
NORTH AND SOUTH AMERICA							
Argentina[26]	2003–2004	611	VAS+TTO	Brazil[27]	2011	3362	TTO
Canada[28]	2012[a]	1145	TTO	Chile[29]	2008	2000	TTO
Trinidad and Tobago[30]	2015	307	DCE/TTO	USA[31]	2002	4048	TTO
OCEANIA							
Australia[32]	2011[a]	417	TTO	New Zealand[33]	1999	1360	VAS

The calculation of the summary number of the EQ-5D-3L is an important element to derive the QALYs, Quality Adjusted Life Years.

2.4 The SF-36

The SF-36 (Short Form Health Survey) is part of the MOS (Medical Outcomes Study), a multi-year and multi-site study that which is interested in explaining the variations in patient health outcomes. SF-36 is developed by Rand Corporation, a researh organization sited in Sweden, whose aim is to find solutions to public challenges in several fields. MOS is one of their active studies in health care. (Rand corporation, 2020)

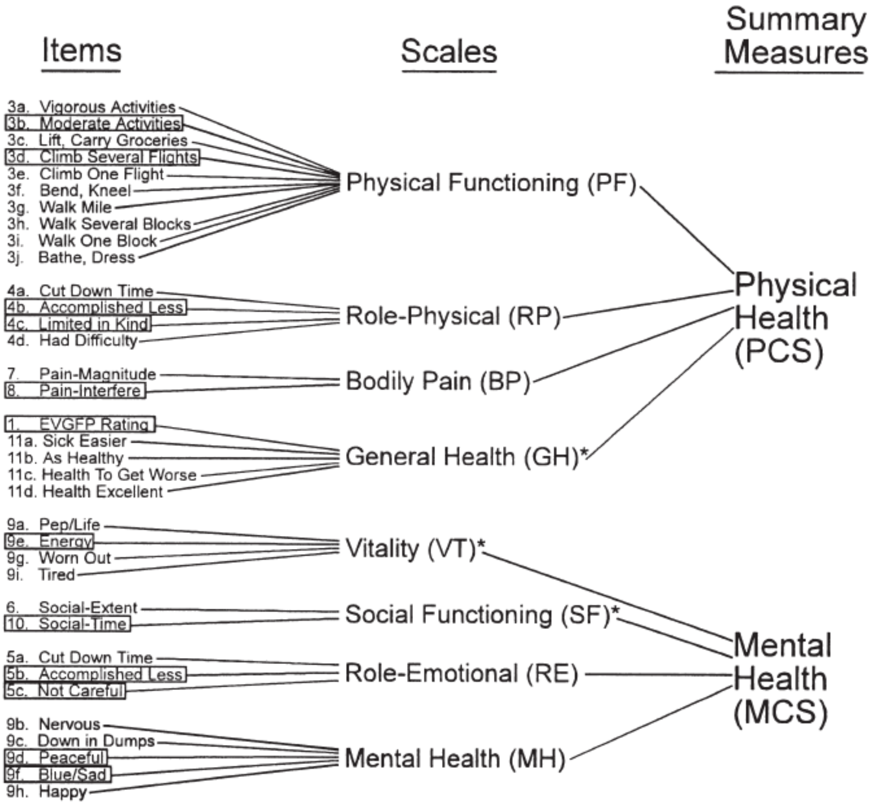
The SF-36 consists of 36 questions which are divided in eight profiles. Its outputs are a eight-scale profile of scores and a summary physical and mental measure. The eight inspected profile were taken from a much larger group from MOS, those contained in the SF-36 have proved to be the most used in the health sector studies. Like the EQ-5D, this questionnaire it is globally recognized as a valid and reliable measure of health and economic comparison. (Ware J.A. and Ganbek, 1998)

There are two versions of the SF-36 and the RAND-36; the questionnaires are basically the same, they have the same questions and items. RAND-36 is free to consult in the RAND website, while the SF-36 is a commercial version. To derive the score of the SF-36 a software is needed, which is available for purchase. (RAND Corporation)

Figure 5 below shows the list of items, Scale and the summary measures present in the SF-36. The complete version of the SF-36 is available in the Appendix 2.

The eight scaled scores, are calculated by obtaining the weighted sums of the questions in each section. Each scale is transformed into a scale from 0 to 100 on the assumption that each question carries equal weight. To a lower score, an higher disablity is connected, the higher the score the less disability, thus, a score of zero would be equivalent to maximum disability and a score of 100 would mean no disability.

Figure 5. The figure shows the taxonomy of the SF-36. The figure was taken from the study of Ware and Gandbek.



3. Methodology

This methodology chapter represents the skeleton of this thesis an it will explain in details the process of the research, the reason behind the choices taken and the scientific background behind it. In order to facilitate the reading, the flow of the discussion will follow a determinate order, to give a suitable construction. The chaptes is basically divided in 3 parts, each of them explaining the rationale behind the research process, the creation of the inclusion criteria and the process of data selection and extraction.

- The first part will familiarize the reader with the concept of the Systematic Literature Review. This part was based on scientific and academic evidences and experiences. The purpose of this part is not only to explain what a SLR is, but to outline every part of it, describing the creation step by step;
- The second part will be dedicated to the PRISMA model. Being this thesis a systematic literature review, a specific and reliable framework is needed. This part present the PRISMA model (and also tells about the study behind the model itself) and show how it has been applied in this work;
- The third part expains the data selection and extraction, in this part the inclusion criteria are revealed and motivated and the tool used to perform the research are described.

3.1 What is a Systematic Literature Review?

The aim of this paragraph is to explain the meaning and the goal of a systematic literature review. Using the words of White A. and Smith k.: “A systematic review retrieves, appraises and summarises all the available evidence on a specific (health) question and then attempts to reconcile and interpret it.” (Systematic literature reviews; Adrian White, Katja Smith. March 2005).

The systematic review aims to avoid previous author bias by selecting scrupolously the sources of the research and by chosing in advance which evidences to use and how to use them. The methods section of these kind of reviews are really important and they must be clear and precise. (White, Shcmidt. 2005)

Table 1 shows the phases of a systematic review. The table is based on 2 articles: The first one is the one from White and Smith (Systematic literature reviews, March 2005) and the second one is the "Cochrane Handbook for Systematic reviews for intervention" (Julian Higgins, Sally Green. 2008) In addition to these guides, this thesis used the guide of PRISMA statement, with the aim of obtaining the most accurate result possible. In the next paragraphs the PRISMA model will be explained and the research methods analyzed.

Table 1

Systematic Review phases	Methods
Step 1: Defining the aim and choose the appropriate methods.	The introduction needs to state what the reader will find in the paper. Appropriate information on the background are needed and explanation of the rationale and the reason for the study.
Step 2: Identifying relevant work	One of the most important part of the review. In this phase the writer decides the source of the search and which articles or studies to focus one. By creating a set of including criteria, he/she will be able to assess whether the researches will be valid for the review.

Step 3: Extraction of relevant data	Once the literature is collected, the writer extracts the most relevant data the data will allow to answer the question posed in the first place. The extraction needs to be coherent, always having the inclusion criteria and the reserch question in mind.
Step 4: Summarise the evidence	This phase highlights the results of the research. It detects and studies differences or similarities within the cases, trends in the literature and any information that serves the aim to answers the research questions.
Step 5: Interprets the evidence	The final part of the review draw the conclusion. In this part, the research questions obtain answers. It must include the weak and strenght point of he original data and of the review. A good conclusion includes implication for future research as well.

3.2 The PRISMA model

This thesis was developed by following the PRISMA model. Developed in 2005 from a group of 29 authors, clinicians, medical editors and consumers, PRISMA is the acronym for "Preferred Reporting Items for Systematic Reviews and Meta Analyses. It is a set of tools which aim to ensure the transparent and complete reporting of systematic reviews and meta-analyses. The most important instruments of PRISMA (and the ones used in this paper) are the PRISMA checklist and the PRISMA flowgram.

The checklist summarizes the information that the authors need to put in the different parts of the paper, starting from the abstract and introduction and concluding with the results and conclusion of the study. We can see the checklist as a guideline that includes all the necessary information that makes a research useful and most important, reliable. Visible in Figure 1, the PRISMA checklist is divided by group of items: a description of the most important will follow.

The Introduction part of the checklist includes the rationale and the objectives of the research. The “rationale” and the “objectives” of a study are the main reasons behind it and thus are relevant parts of the PRISMA checklist; with the rationale being the motivation of the paper and the objectives the aims or the answers that the study wants to find. It is important to state and clear what these two items represent, in order to justify ht meaning of the research and the value i twill bring to the readers.

Another important part of the PRISMA checklist is dedicated to the methods of the research, a crucial part of any study or review. The checklist emphasizes the importance of a protocol for the research, whether it is a new one or based on existing studies. The protocol in a research assures its quality. Publication of a protocol for a review reduces the impact of review authors’ biases, enhance the transparency of the methods and reduces the potential of duplication. (Liberati A. et al, 2005).

3.3 The PRISMA flow diagram

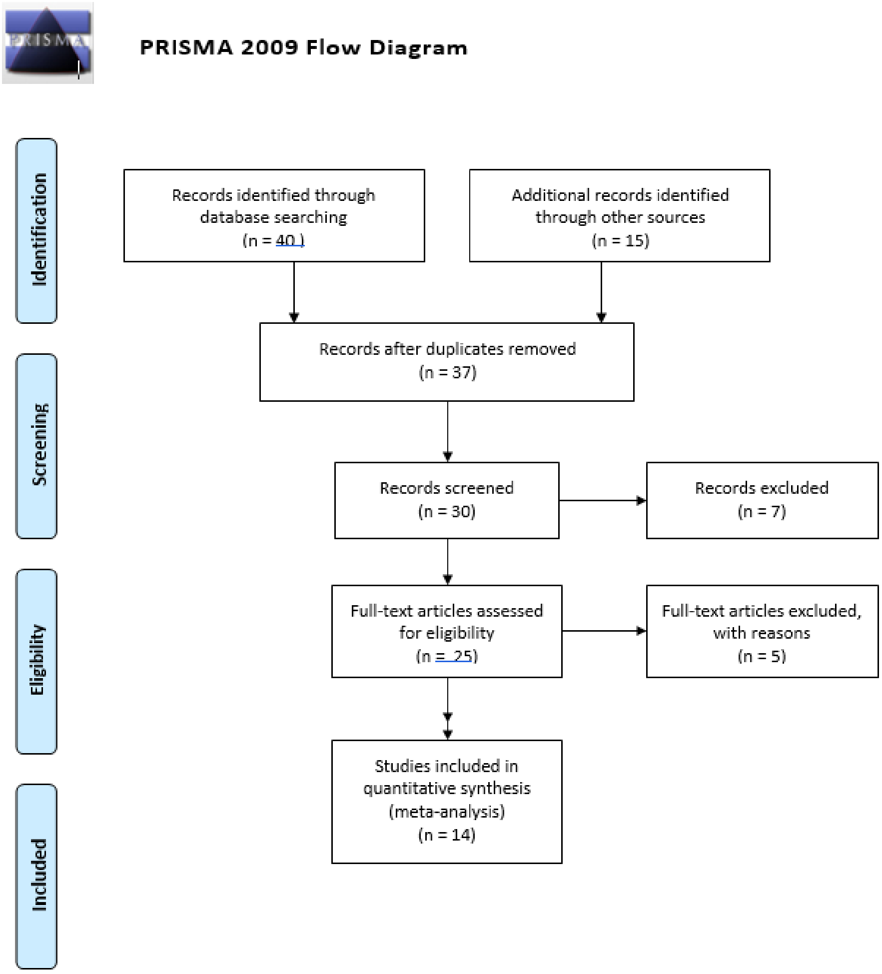
The PRISMA model involves a tool called “PRISMA flow diagram”, which describes the process of choosing the studies and articles included in a research. We can think this diagram as the skeleton of the research, but it requires a valid set of eligibility criteria, in addition to the rational and objective of the research described above, to function properly. The diagram is divided in 4 phases: Identification, Screening, Eligibility and the Inclusion.

The identification phase explains the origin of the sources of the study. It says how many papers were grouped in the first part of the research and if any further paper was added from different sources.

The screening phase is the first filter of the process. In this phase, any duplicated is removed from the study and the remaining papers are screened and studied.

During the Eligibility phase, all the abstracts screened in the previous phase are evaluated. Those who are not consistent with the eligibility criteria are excluded from the research; afterwards, the full texts are read and analyzed. A second phase of skimming leads to the last phase. During this skimming phase, all the full texts who did not met the eligibility criteria will be excluded from the research, the reason for the exclusion is to be motivated. The final phase groups all the articles that have been suitable and thus, will be the base of the research. Figure 6 represents the flow diagram of this thesis, in the next paragraph the methods of the research will be described.

Figure 6. The PRISMA flow diagram used in this thesis



3.4 The research methods and inclusion criteria

Figure 7 shows the inclusion and the exclusion criteria

Inclusion and exclusion criteria	Rationale
1. Articles wìhaving main focus in use of PROMs are included 2. The article must be taken from a peer-reviewed journal or source 3. The paper must be in english 4. Articles studying the effectiveness of PROMs in routine care and as a comparison measure are included	1. Ensuring consistency with research questions, 2. Ensuring validity, reliabilty and impact on the health sector; 3. Ensuring accessibility and ful understanding 4. This criteria narrows the field of search and ensure clearer evidences

According to White and Schmidt, the inclusion criteria of a systematic literature review must be guided by the research question, and determined before the data are gathered, in order to avoid any bias from the author. Plius, they will facilitate the work of the author, who will be able to underdstand whether an article is able to provide proper data from its abstract.

Initially, a first research was carried out, with the only purpose to familiarize the author with the topic, right after the first research, the question and sub-question were written down. subsequently, the inclusion criteria were chosen independently by the author. This thesis has the limitation of being conducted by just one author, later in the thesis, this aspect will be discussed, as it is might cause bias. Figure 7 shows the inclusion criteria and their rationale.

The material used for the introduction chapter about patient centered care was provided by Professor Maria Helena Mourino Nunes, who is a co-relator of this thesis as well. Other source of ispiration have been found in the bibliographies of relevant citations, which were screened for further articles of relevance.

After these steps were completed, the main research started. The main sources of the research were 3 databases: PubMed, Google Scholar, the database of Journal of Patient Reported Outcomes of ISOQOL. The main keywords used for the research were:

"Patient Reported Outcomes", "Health related quality of life", "Generic PROMs", "Disease Specific PROMs", "Routine clinical settings". To narrow the research field the terms have been used together in some of the research session. I.e PROMs in routine clinical settings.

As the flowgram in the previous paragraph shows, only 40 paper were included in the first phase of the research. 15 more were added by consulting the literature background used for the introduction chapter. A possible explanation of the relatively low number of papers is that the diffusion of PROMs into clinical settings started to spread recently. Another limit correlated is that the research method had been conducted only via online databases, this has drastically reduced the number of eligible evidences. Due to covid pandemic, the setting of real-life meeting and the collection of different source of data (i.e. face to face interviews) was not possible.

However, the intention of the author was to collect data from peer reviewed journals, the reason for that is explained in the paper from White and Schimdt, about the reliability of a Systematic Literature review, and in PRISMA statement.

3.5 Data extraction

To keep track of the literature and report it in the most correct and valid way possible, the reference manager program Zotero was used. Zotero gives to the user the possibility to create different in folder in the main literature research. 3 different folder were created. The first one collected the material used for the introduction and literature background part, the second one stored the literature about routine care of PROMs and finally, the third part included the literature used for the topic of PROMs used as a comparison tool.

At the end of the research process, a total of 14 papers met the inclusion and exclusion criteria. The following Table is the list of these papers.

Table x. In this table, the core of the literature of this thesis will be presented by Author's name, title of the article, Year of publication and the source. The papers are sorted by publication date

#	Authors name	Title of the article	Year	Journal
1	Greenhalgh et al.	The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory?	2005	Social science and Medicine
2	Stover et al.	Using an implementation science approach to implement and evaluate patient-reported outcome measures (PROM) initiatives in routine care settings	2010	Springer Open
3	Bausewein et al.	Implementing patient reported outcome measures (PROMs) in palliative care - users' cry for help	2011	Springer Open
4	Snyder et al.	Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations	2012	Springer Open
5	Weldrin et al.	Patient-Reported Outcomes (Pro s) and Patient-Reported Outcome Measures (Prom s)	2013	LA press
6	Santana et al.	Framework to assess the effects of using patient-reported outcome measures in chronic care management	2014	Springer Open
7	Reeve	ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research	2013	Journal of Patient Reported Outcomes
8	Kyte et al.	An introduction to patient-reported outcome measures(PROMs) in physiotherapy	2015	Physiotherapy
9	Falavigna et al.	Current Status of Worldwide Use of Patient-Reported Outcome Measures (PROMs) in Spine Care	2017	World Neurosurgery
10	Recinos et al.	Patient Satisfaction with Collection of Patient-Reported Outcome Measures in Routine Care	2017	Springer Open

11	Basch et al.	Implementation of Patient reported outcomes in routine clinical care	2018	American society of clinical oncolgy publications
12	Dawson et al.	The routine use of patient reported outcomes in health care settings	2018	British medical Journal
13	Cole et al.	Using postal questionnaires to evaluate physical activity and diet behaviour change: case study exploring implications of valid responder characteristics in interpreting intervention outcomes	2018	BioMed Central
14	Greenhalgh et al.	How do patient reported outcome measures (PROMs) support clinician-patient communication and patient care? A realist synthesis	2018	Journal of Patient Reported Outcomes

4. Analysis

The intention of this chapter is to answer the sub questions in chapter 1, analyzing the collected qualitative data. Basically, this chapter will provide the tool to answer the main question of the thesis, which will finally find an answer in the Dicussion chapter.

- “What are patients and health care professional opinion and experiences about the use of PROMs?”
- “Which challenges do the adopters of PROMs need to overcome?”

The question above guided the research process, the collection of the data and the creation of the inclusion criteria. In the idea of the author, finding the answers to the sub questions above, will lead the way for achieving the purpose of the thesis

A first peculiar characteristic of this collection is the date of the publications; the first paper was publicated in 2005, while the other ones are subsequent. Even though the timeline of the research was from inception to 2020, the topic of the application of PROM in routine clinical setting is relatively new. This data confirms what was observed in the literature background chapter. It is in fact in the first decade of 2000s that the use of PROMs in routine clinical settings started to spread and gained a definitive boost after the decisions of the UK government to include reported outcomes, in the first half of 2000s. (Evans et al.) However, other countries like United States and Sweden started to implement the use of PROMs on a national level as well. (Black et al.)

The trend evolved in the last 15 years and the interest about PROMs has risen sharply, together with their use in clinical trials and in clinical routine use. (Weldrin et al.) Observing the data collected, some themes were recurring, regardless of the disease / treatment and the country where the paper was written.

Firstly, the effectiveness of PROMs as a patient-centered tool is widely confirmed by experts in the field and in the literature. The authors of the analyzed papers recognize the usefulness, effectiveness and ability to adapt to different context, whether to different health systems or different treatment. However, at the same time, to get the best out of the use of PROMs, there is a need for an appropriate preparation phase and a rigid framework of rules and prerequisites. In absence of this, there is a risk that the adoption of these tools will be ineffective and lead to estimation errors. Furthermore, the choice of the most appropriate PROMs it should not be underestimated.

To go more into details, the paper of Basch et al. provides several good examples. In the frame of the eRAPID system in England and the use of PROMs in the region of Ontario, Canada. The eRAPID system allowed online patient reporting during and beyond cancer treatment. The approach has facilitated and speeded up the collection of data from patients and the results over time have been largely positive from both a patient and health staff perspective: the latest report on the study results dates back to January 8th 2021 and has been shown that patients followin the eRAPID approach improved physical well-being and self-efficacy in a patient population predominantly treated with curative intent, this happen by ensuring the cost-effectiveness and without increasing hospital workload. (Absolom K. Et al, Journal of Clinical Oncology, 2021)

Previous updates on the results of this system had been positive as well. Basch and his colleagues explain the key to success of this process which relies in the development phase. The development phase prepared the field for the success of the eRAPID system.

Here is a summary of the step carried on during the development phase:

- Firstly, a robust and secure online system was created. This system had the aim to facilitate the collection and storing of data, this database was connected to individual Electronic health records;
- A process mapping of patient treatment pathways was performed, to understand where and hot the eRAPID approach would best fit. Furthermore the proper key professional were identified;
- A selection of the proper outcomes measure was performed,
- Lastly, both patients and professionals received training on how the system worked. Patients were showed sample questions and graph of responses while staff received an overall presentation of the project, its functioning and aims.

The case of eRAPID is emblematic and describes the best strategy to apply PROMs in a clinical routine setting. The findings in Basch study found confirmation in the other papers in this literature review. The work of Black et al., for instance highlighted the challenge of reducing cost recurring more to digital collection of data or even online, allowing the patient to fill the records from home.

However the study of Cole et al. showed some criticism. In this paper, a follow up study using two different PROMs measure was conducted. The area of study was the tracking of leisure time and physical activity in patients with heart coronary disease. At the end of the 18 months period of the study, part of the data was missing, meaning that some of the patients did not answer to the questionnaire, furthermore, a consistent number of answers were not valid, and therefore it was impossible for the professional to assess whether a health improvement was achieved or not. Cole found that the majority of the missing answer came from patient with lower education and income (Black et al. agree, as the lower rate of the answer is a limitaton) than the ones who did provide an answer. The understanding of the questions was a problem too, as a number of answers was not valid. eRAPID approach coped this challenge by educate the patient in the development phase.

The need for a rigid framework and development phase was pointed out by the study of Dawson et al., details, the choice of the proper PROMs is of absolute importance for Dawson and his colleagues. The process of choice of the PROMs must be clear and the health professional need to have in mind the precise outcomes they want to measure. It might sounds logical, but this is not easy at all, as there is a vaste number of developed PROMs, especially in the last decade (Black). To sum up, in order to choose a proper outcome measure a resarch question needs to be conducted and data from systematic reviews on the topic will facilitate the choce of the right tool. "This approach will help guide and standardise methods of data collection and aid the design of any associated database for storing data, as well as inform consideration of inclusion and exclusion criteria.)" (Dawson et al.)

Finally, a multitude of authors (Snyder et al, Evans et al., Dawason et al, Basch et al.) agreed with the idea of adopting guidelines for the implementation of PROMs. In the literature are found those of ISOQOL and the PROMIS program.
The need for a specific and tailored framework is evident from the literature.

Ultimately the work of Greenhalgh et, Santana et al. and Bausewein et al. highlighted the importance that proms have had for the patient health self-perception and improvement in patient-clinician communicatio.

Especially Greenlhagh found that the "impersonal" nature of some of the PROMs used, helped them to raise was helpful to them to raise issues to the clinicians.

5. Discussion

The research question in chapter 1 asked:

"Why the use of PROMs remains mostly confined to clinical trials and does not seem to be able to spread into clinical routine practices worldwide?"

Literature research of this thesis provided evidences on the effectiveness of PROMs, though limited, really promising. The example of eRAPID shows that PROMs are able to improve the clinical condition and the health related quality of life of the patients. However, this goal comes if preceded by a thorough study of the case, of the population, and all the specific aspect of a certain disease. A common reason of failure, as is a poor development phase and research phase.

Giving the evidences collected in the research, an aswer to the question is that a widely use of PROMs into clinical setting has met several challenges. The main of these concerned the workflow and the training of the health staff and the education of patient as well.

Furthermore logistic and economical challenges has been found, the solution this problem is usually hard to be implemented.

The inclusion of PROMs in clinical care is a relatively new topic anyway, and it is gaining more and more attention throught the world, with due time, it is likely that these challenges will be overcomed.

5.1 Limitation of the study

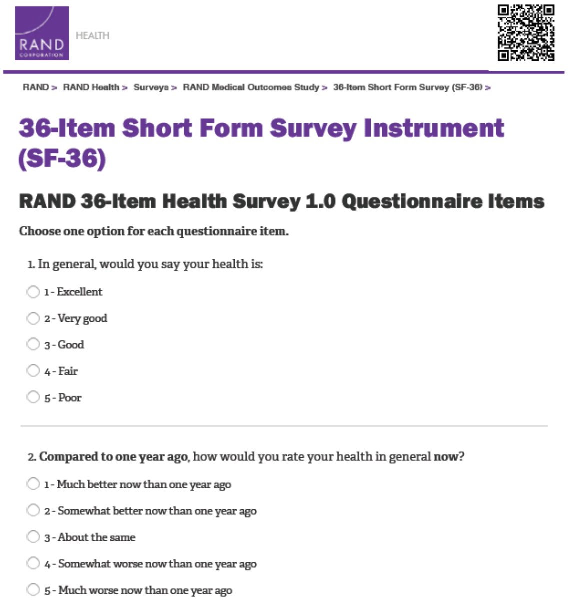
Several limitation affects this study, first of all this is a single author study and the fact that just one person took care of the research strategy, can be a reason for bias and it can narrow the point of view of the research. This thesis is based on qualitative secondary data, though the source is peer-reviewed, it stops its focus on the theoretical aspect by not taking into account empirical data. Due to covid pandemic, the research of different empircical and qualitative data was not feasible.

5.2 Further improvements to the study

Collecting data form real-life cases could help in strenghten the output of the thesis, the data collected did show shared trends in the literature and side these statement with proper calculation, regression models and studie in real-life settings would help to confirm the findings.

6. Appendix

Appendix 1.



RAND > RAND Health > Surveys > RAND Medical Outcomes Study > 36-Item Short Form Survey (SF-36) >

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

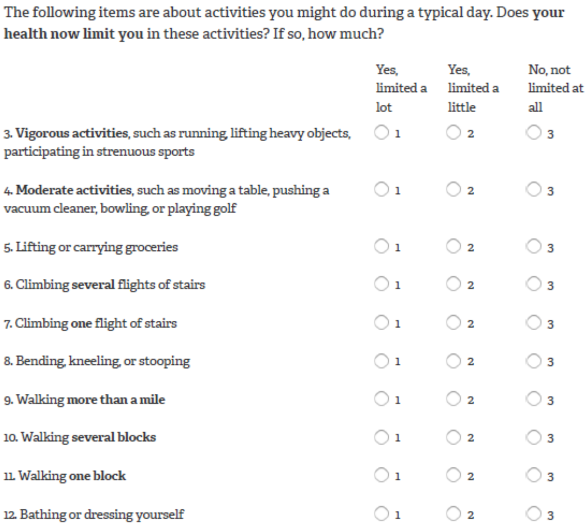
Choose one option for each questionnaire item.

1. In general, would you say your health is:

○ 1 - Excellent
○ 2 - Very good
○ 3 - Good
○ 4 - Fair
○ 5 - Poor

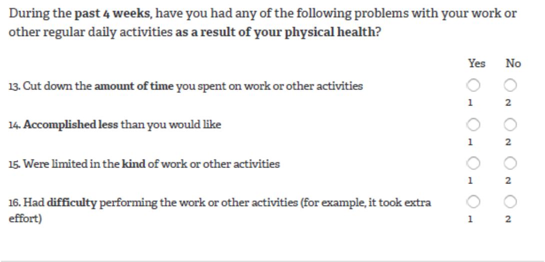
2. **Compared to one year ago,** how would you rate your health in general **now**?

○ 1 - Much better now than one year ago
○ 2 - Somewhat better now than one year ago
○ 3 - About the same
○ 4 - Somewhat worse now than one year ago
○ 5 - Much worse now than one year ago



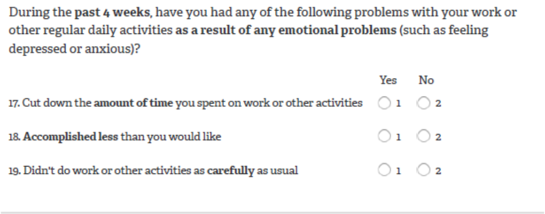
The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	○ 1	○ 2	○ 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○ 1	○ 2	○ 3
5. Lifting or carrying groceries	○ 1	○ 2	○ 3
6. Climbing **several** flights of stairs	○ 1	○ 2	○ 3
7. Climbing **one** flight of stairs	○ 1	○ 2	○ 3
8. Bending, kneeling, or stooping	○ 1	○ 2	○ 3
9. Walking **more than a mile**	○ 1	○ 2	○ 3
10. Walking **several blocks**	○ 1	○ 2	○ 3
11. Walking **one block**	○ 1	○ 2	○ 3
12. Bathing or dressing yourself	○ 1	○ 2	○ 3



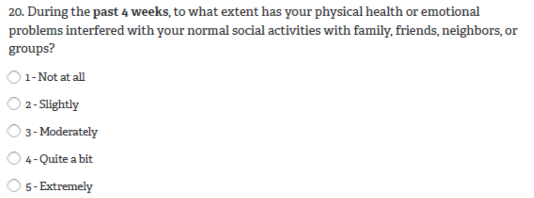
During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
14. **Accomplished less** than you would like	○ 1	○ 2
15. Were limited in the **kind** of work or other activities	○ 1	○ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2



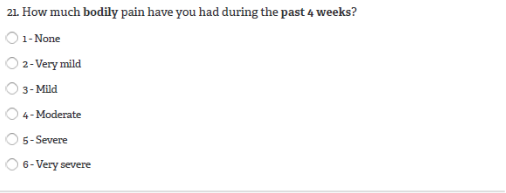
During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
18. **Accomplished less** than you would like	○ 1	○ 2
19. Didn't do work or other activities as **carefully** as usual	○ 1	○ 2



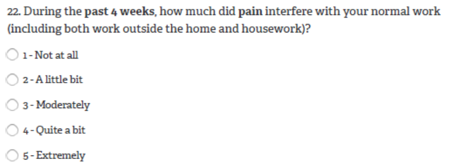
20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

○ 1 - Not at all
○ 2 - Slightly
○ 3 - Moderately
○ 4 - Quite a bit
○ 5 - Extremely



21. How much **bodily** pain have you had during the **past 4 weeks**?

○ 1 - None
○ 2 - Very mild
○ 3 - Mild
○ 4 - Moderate
○ 5 - Severe
○ 6 - Very severe



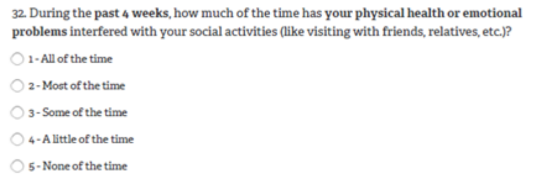
22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

○ 1 - Not at all
○ 2 - A little bit
○ 3 - Moderately
○ 4 - Quite a bit
○ 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

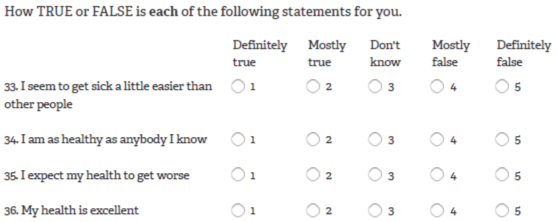
How much of the time during the **past 4 weeks...**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
24. Have you been a very nervous person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
25. Have you felt so down in the dumps that nothing could cheer you up?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
26. Have you felt calm and peaceful?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
27. Did you have a lot of energy?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
28. Have you felt downhearted and blue?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
29. Did you feel worn out?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
30. Have you been a happy person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
31. Did you feel tired?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6



32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

○ 1 - All of the time
○ 2 - Most of the time
○ 3 - Some of the time
○ 4 - A little of the time
○ 5 - None of the time



How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	○ 1	○ 2	○ 3	○ 4	○ 5
34. I am as healthy as anybody I know	○ 1	○ 2	○ 3	○ 4	○ 5
35. I expect my health to get worse	○ 1	○ 2	○ 3	○ 4	○ 5
36. My health is excellent	○ 1	○ 2	○ 3	○ 4	○ 5

REFERENCES

Basch, Ethan, Lisa Barbera, Carolyn L. Kerrigan, and Galina Velikova. 2018. 'Implementation of Patient-Reported Outcomes in Routine Medical Care'. American Society of Clinical Oncology Educational Book. American Society of Clinical Oncology. Annual Meeting 38:122–34. doi: 10.1200/EDBK_200383.

Black, Nick. 2013. 'Patient Reported Outcome Measures Could Help Transform Healthcare'. BMJ (Clinical Research Ed.) 346:f167. doi: 10.1136/bmj.f167.

Borg, Sixten, Katarina Eeg-Olofsson, Bo Palaszewski, Maria Svedbo Engström, Ulf-G. Gerdtham, and Soffia Gudbjörnsdottir. 2019. 'Patient-Reported Outcome and Experience Measures for Diabetes: Development of Scale Models, Differences between Patient Groups and Relationships with Cardiovascular and Diabetes Complication Risk Factors, in a Combined Registry and Survey Study in Sweden'. BMJ Open 9(1). doi: 10.1136/bmjopen-2018-025033.

Boye, Kristina S., Louis S. Matza, Brooke M. Currie, and Karin S. Coyne. 2020. 'Validity and Analysis of the Diabetes Injection Device Preference Questionnaire (DID-PQ)'. Journal of Patient-Reported Outcomes 4(1):104. doi: 10.1186/s41687-020-00266-x.

Bradley, Clare, Eveline Eschwège, Pedro de Pablos-Velasco, Klaus G. Parhofer, Dominique Simon, Hans Vandenberghe, and Linda Gönder-Frederick. 2018. 'Predictors of Quality of Life and Other Patient-Reported Outcomes in the PANORAMA Multinational Study of People With Type 2 Diabetes'. Diabetes Care 41(2):267–76. doi: 10.2337/dc16-2655.

Brasil, Fábio, Andreia Mara Brolezzi Brasil, Rodrigo Augusto de Paula e Souza, Roberto Pontarolo, Cassyano Januário Correr, Fábio Brasil, Andreia Mara Brolezzi Brasil, Rodrigo Augusto de Paula e Souza, Roberto Pontarolo, and Cassyano Januário Correr. 2015. 'Development of the Brazilian Brief Version of the Diabetes Quality of Life Measure (DQOL-Brazil-8)'. Revista Brasileira de Epidemiologia 18(4):943–52. doi: 10.1590/1980-5497201500040021.

Brodney, Suzanne, K. D. Valentine, Floyd J. Fowler, and Michael J. Barry. 2020. 'Validation of the 3-Item What Engagement Looks Like (WELL) Scale in Patients with Diabetes'. Journal of Patient-Reported Outcomes 4(1):57. doi: 10.1186/s41687-020-00225-6.

Bryan, Stirling, Jennifer Davis, James Broesch, Mary M. Doyle-Waters, Steven Lewis, Kim Mcgrail, Margaret J. McGregor, Janice M. Murphy, and Rick Sawatzky. 2014. 'Choosing Your Partner for the PROM: A Review of Evidence on Patient-Reported Outcome Measures for Use in Primary and Community Care'. Healthcare Policy 10(2):38–51.

Burström, Kristina, Magnus Johannesson, and Finn Diderichsen. 2006. 'A Comparison of Individual and Social Time Trade-off Values for Health States in the General Population'. Health Policy 76(3):359–70. doi: 10.1016/j.healthpol.2005.06.011.

Chen, Yu Ting, Yan Zhi Tan, Mcvin Cheen, and Hwee-Lin Wee. 2019. 'Patient-Reported Outcome Measures in Registry-Based Studies of Type 2 Diabetes Mellitus: A Systematic Review'. Current Diabetes Reports 19(11):135. doi: 10.1007/s11892-019-1265-8.

Cole, Judith A., Paddy Gillespie, Susan M. Smith, Molly Byrne, Andrew W. Murphy, and Margaret E. Cupples. 2014. 'Using Postal Questionnaires to Evaluate Physical Activity and Diet Behaviour Change: Case Study Exploring Implications of Valid Responder Characteristics in Interpreting Intervention Outcomes'. BMC Research Notes 7. doi: 10.1186/1756-0500-7-725.

Dawson, Jill, Helen Doll, Ray Fitzpatrick, Crispin Jenkinson, and Andrew J. Carr. 2010. 'The Routine Use of Patient Reported Outcome Measures in Healthcare Settings'. BMJ 340. doi: 10.1136/bmj.c186.

Dennick, Kathryn, Jackie Sturt, and Jane Speight. 2017. 'What Is Diabetes Distress and How Can We Measure It? A Narrative Review and Conceptual Model'. Journal of Diabetes and Its Complications 31(5):898–911. doi: 10.1016/j.jdiacomp.2016.12.018.

Devlin, Nancy J., David Parkin, and John Browne. 2010. 'Patient-Reported Outcome Measures in the NHS: New Methods for Analysing and Reporting EQ-5D Data'. Health Economics 19(8):886–905. doi: https://doi.org/10.1002/hec.1608.

El Achhab, Youness, Chakib Nejjari, Mohamed Chikri, and Badiaa Lyoussi. 2008. 'Disease-Specific Health-Related Quality of Life Instruments among Adults Diabetic: A Systematic Review'. Diabetes Research and Clinical Practice 80(2):171–84. doi: 10.1016/j.diabres.2007.12.020.

Evans, Jonathan P., Alexander Smith, Chris Gibbons, Jordi Alonso, and Jose M. Valderas. 2018. 'The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS): A View from the UK'. Patient Related Outcome Measures 9:345–52. doi: 10.2147/PROM.S141378.

Falavigna, Asdrubal, Diego Cassol Dozza, Alisson R. Teles, Chung Chek Wong, Giuseppe Barbagallo, Darrel Brodke, Abdulaziz Al-Mutair, Zoher Ghogawala, and K. Daniel Riew. 2017. 'Current Status of Worldwide Use of Patient-Reported Outcome Measures (PROMs) in Spine Care'. World Neurosurgery 108:328–35. doi: 10.1016/j.wneu.2017.09.002.

Farmer, Ruth, Rohini Mathur, Krishnan Bhaskaran, Sophie V. Eastwood, Nish Chaturvedi, and Liam Smeeth. 2018. 'Promises and Pitfalls of Electronic Health Record Analysis'. Diabetologia 61(6):1241–48. doi: 10.1007/s00125-017-4518-6.

Farnik, Małgorzata, and Władys aw Pierzchała. 2012. 'Instrument Development and Evaluation for Patient-Related Outcomes Assessments'. Patient Related Outcome Measures 3:1–7. doi: 10.2147/PROM.S14405.

Franch-Nadal, Josep, Elena Labrador Barba, M. Carmen Gómez-García, Pilar Buil-Cosiales, José Manuel Millaruelo, and María Luisa Orera Peña. 2015. 'Patient-Reported Outcomes in Type 2 Diabetes Mellitus: Patients' and Primary Care Physicians' Perspectives in the Spanish Health Care System'. Patient Preference and Adherence 9:1413–22. doi: 10.2147/PPA.S87005.

Greenhalgh, Joanne, Kate Gooding, Elizabeth Gibbons, Sonia Dalkin, Judy Wright, Jose Valderas, and Nick Black. 2018. 'How Do Patient Reported Outcome Measures (PROMs) Support Clinician-Patient Communication and Patient Care? A Realist Synthesis'. Journal of Patient-Reported Outcomes 2:42. doi: 10.1186/s41687-018-0061-6.

Greenhalgh, Joanne, Andrew F. Long, and Rob Flynn. 2005. 'The Use of Patient Reported Outcome Measures in Routine Clinical Practice: Lack of Impact or Lack of Theory?' Social Science & Medicine 60(4):833–43. doi: 10.1016/j.socscimed.2004.06.022.

Gries, Katharine, Pamela Berry, Magdalena Harrington, Mabel Crescioni, Mira Patel, Katja Rudell, Shima Safikhani, Sheryl Pease, and Margaret Vernon. 2018. 'Literature Review to Assemble the Evidence for Response Scales Used in Patient-Reported Outcome Measures'. Journal of Patient-Reported Outcomes 2(1):41. doi: 10.1186/s41687-018-0056-3.

Hammert, Warren C., and Ryan P. Calfee. 2020. 'Understanding PROMIS'. The Journal of Hand Surgery 45(7):650–54. doi: 10.1016/j.jhsa.2020.03.016.

Higgins, Julian PT, and Sally Green. n.d. 'Cochrane Handbook for Systematic Reviews of Interventions : Cochrane Book Series'. 674.

Hutchings, Hayley A., and Laith Alrubaiy. 2017. 'Patient-Reported Outcome Measures in Routine Clinical Care: The PROMise of a Better Future?' Digestive Diseases and Sciences 62(8):1841–43. doi: 10.1007/s10620-017-4658-z.

Ishii, Hitoshi, Yasuo Terauchi, Hideaki Jinnouchi, Masanori Taketsuna, Masakazu Takeuchi, and Takeshi Imaoka. 2013. 'Effects of Insulin Changes on Quality of Life and Glycemic Control in Japanese Patients with Type 2 Diabetes Mellitus: The Insulin-Changing Study Intending to Gain Patients' Insights into Insulin Treatment with Patient-Reported Health Outcomes in Actual Clinical Treatments (INSIGHTs) Study'. Journal of Diabetes Investigation 4(6):560–70. doi: 10.1111/jdi.12086.

Karimi, Milad, and John Brazier. 2016. 'Health, Health-Related Quality of Life, and Quality of Life: What Is the Difference?' PharmacoEconomics 34(7):645–49. doi: 10.1007/s40273-016-0389-9.

Kendrick, Tony, Magdy El-Gohary, Beth Stuart, Simon Gilbody, Rachel Churchill, Laura Aiken, Abhishek Bhattacharya, Amy Gimson, Anna L. Brütt, Kim de Jong, and Michael Moore. 2016. 'Routine Use of Patient Reported Outcome Measures (PROMs) for Improving Treatment of Common Mental Health Disorders in Adults'. Cochrane Database of Systematic Reviews (7). doi: 10.1002/14651858.CD011119.pub2.

Kyte, D. G., M. Calvert, P. J. van der Wees, R. ten Hove, S. Tolan, and J. C. Hill. 2015. 'An Introduction to Patient-Reported Outcome Measures (PROMs) in Physiotherapy'. Physiotherapy 101(2):119–25. doi: 10.1016/j.physio.2014.11.003.

Lee, Jiyeon, Eun-Hyun Lee, Chun-Ja Kim, and Seung Hei Moon. 2015. 'Diabetes-Related Emotional Distress Instruments: A Systematic Review of Measurement Properties'. International Journal of Nursing Studies 52(12):1868–78. doi: 10.1016/j.ijnurstu.2015.07.004.

Liberati, A., D. G. Altman, J. Tetzlaff, C. Mulrow, P. C. Gotzsche, J. P. A. Ioannidis, M. Clarke, P. J. Devereaux, J. Kleijnen, and D. Moher. 2009. 'The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Healthcare Interventions: Explanation and Elaboration'. BMJ 339(jul21 1):b2700–b2700. doi: 10.1136/bmj.b2700.

Matza, Louis S., Kristina S. Boye, Katie D. Stewart, Rosirene Paczkowski, Jessica Jordan, and Lindsey T. Murray. 2018. 'Development of the Diabetes Injection Device Experience Questionnaire (DID-EQ) and Diabetes Injection Device Preference Questionnaire (DID-PQ)'. Journal of Patient-Reported Outcomes 2(1):43. doi: 10.1186/s41687-018-0068-z.

Matza, Louis S., Katie D. Stewart, Rosirene Paczkowski, Karin S. Coyne, Brooke Currie, and Kristina S. Boye. 2018. 'Psychometric Evaluation of the Diabetes Injection Device Experience Questionnaire (DID-EQ) and Diabetes Injection Device Preference Questionnaire (DID-PQ)'. Journal of Patient-Reported Outcomes 2(1):44. doi: 10.1186/s41687-018-0064-3.

McKenna, Stephen P. 2011. 'Measuring Patient-Reported Outcomes: Moving beyond Misplaced Common Sense to Hard Science'. BMC Medicine 9:86. doi: 10.1186/1741-7015-9-86.

Moher, David, Larissa Shamseer, Mike Clarke, Davina Ghersi, Alessandro Liberati, Mark Petticrew, Paul Shekelle, Lesley A. Stewart, and PRISMA-P Group. 2015. 'Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 Statement'. Systematic Reviews 4(1):1. doi: 10.1186/2046-4053-4-1.

Monica, 1776 Main Street Santa, and California 90401-3208. n.d. 'RAND Corporation Provides Objective Research Services and Public Policy Analysis'. Retrieved 15 January 2021 (https://www.rand.org).

Murphy, Mairead, Sandra Hollinghurst, and Chris Salisbury. 2018. 'Identification, Description and Appraisal of Generic PROMs for Primary Care: A Systematic Review'. BMC Family Practice 19(1):41. doi: 10.1186/s12875-018-0722-9.

Porter, Michael E. 2010. 'What Is Value in Health Care?' Http://Dx.Doi.Org/10.1056/NEJMp1011024. Retrieved 9 December 2020 (https://www.nejm.org/doi/10.1056/NEJMp1011024).

Recinos, Pablo F., Cheryl J. Dunphy, Nicolas Thompson, Jesse Schuschu, John L. Urchek, and Irene L. Katzan. 2017. 'Patient Satisfaction with Collection of Patient-Reported Outcome Measures in Routine Care'. Advances in Therapy 34(2):452–65. doi: 10.1007/s12325-016-0463-x.

Reeve, Bryce B., Kathleen W. Wyrwich, Albert W. Wu, Galina Velikova, Caroline B. Terwee, Claire F. Snyder, Carolyn Schwartz, Dennis A. Revicki, Carol M. Moinpour, Lori D. McLeod, Jessica C. Lyons, William R. Lenderking, Pamela S. Hinds, Ron D. Hays, Joanne Greenhalgh, Richard Gershon, David Feeny, Peter M. Fayers, David Cella, Michael Brundage, Sara Ahmed, Neil K. Aaronson, and Zeeshan Butt. 2013. 'ISOQOL Recommends Minimum Standards for Patient-Reported Outcome Measures Used in Patient-Centered Outcomes and Comparative Effectiveness Research'. Quality of Life Research: An International Journal of Quality of Life

Aspects of Treatment, Care and Rehabilitation 22(8):1889–1905. doi: 10.1007/s11136-012-0344-y.

Rubin, Richard R., and Mark Peyrot. 1999. 'Quality of Life and Diabetes'. Diabetes/Metabolism Research and Reviews 15(3):205–18. doi: https://doi.org/10.1002/(SICI)1520-7560(199905/06)15:3<205::AID-DMRR29>3.0.CO;2-O.

Rubin, Richard R., Mark Peyrot, and Linda M. Siminerio. 2006. 'Health Care and Patient-Reported Outcomes: Results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study'. Diabetes Care 29(6):1249–55. doi: 10.2337/dc05-2494.

Saisho, Yoshifumi. 2018. 'Use of Diabetes Treatment Satisfaction Questionnaire in Diabetes Care: Importance of Patient-Reported Outcomes'. International Journal of Environmental Research and Public Health 15(5). doi: 10.3390/ijerph15050947.

Santana, Maria-Jose, and David Feeny. 2014. 'Framework to Assess the Effects of Using Patient-Reported Outcome Measures in Chronic Care Management'. Quality of Life Research 23(5):1505–13. doi: 10.1007/s11136-013-0596-1.

Schmidt, C. B., B. J. Potter van Loon, A. C. M. Vergouwen, F. J. Snoek, and A. Honig. 2018. 'Systematic Review and Meta-Analysis of Psychological Interventions in People with Diabetes and Elevated Diabetes-Distress'. Diabetic Medicine: A Journal of the British Diabetic Association. doi: 10.1111/dme.13709.

Skovlund, Soren E., TH Lichtenberg, D. Hessler, and N. Ejskjaer. 2019. 'Can the Routine Use of Patient-Reported Outcome Measures Improve the Delivery of Person-Centered Diabetes Care? A Review of Recent Developments and a Case Study'. Current Diabetes Reports 19(9):84. doi: 10.1007/s11892-019-1190-x.

Snyder, Claire F., Neil K. Aaronson, Ali K. Choucair, Thomas E. Elliott, Joanne Greenhalgh, Michele Y. Halyard, Rachel Hess, Deborah M. Miller, Bryce B. Reeve, and Maria Santana. 2012. 'Implementing Patient-Reported Outcomes Assessment in Clinical Practice: A Review of the Options and Considerations'. Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation 21(8):1305–14. doi: 10.1007/s11136-011-0054-x.

Stover, Angela M., Lotte Haverman, Hedy A. van Oers, Joanne Greenhalgh, Caroline M. Potter, Sara Ahmed, Joanne Greenhalgh, Elizabeth Gibbons, Lotte Haverman, Kimberly Manalili, Caroline Potter, Natasha Roberts, Maria Santana, Angela M. Stover, Hedy van Oers, and On behalf of the ISOQOL PROMs/PREMs in Clinical Practice Implementation Science Work Group. 2020. 'Using an Implementation Science Approach to Implement and Evaluate Patient-Reported Outcome Measures (PROM) Initiatives in Routine Care Settings'. Quality of Life Research. doi: 10.1007/s11136-020-02564-9.

Street, Richard L. 2013. 'How Clinician–Patient Communication Contributes to Health Improvement: Modeling Pathways from Talk to Outcome'. Patient Education and Counseling 92(3):286–91. doi: 10.1016/j.pec.2013.05.004.

Ware, John E., and Barbara Gandek. 1998. 'Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project'. Journal of Clinical Epidemiology 51(11):903–12. doi: 10.1016/S0895-4356(98)00081-X.

Weldring, Theresa, and Sheree M. S. Smith. 2013. 'Article Commentary: Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs)'. Health Services Insights 6:HSI.S11093. doi: 10.4137/HSI.S11093.

Wennberg, John E. 2010. 'Outcomes Research, Cost Containment, and the Fear of Health Care Rationing'. Http://Dx.Doi.Org/10.1056/NEJM199010253231710. Retrieved 10 January 2021 (https://www.nejm.org/doi/pdf/10.1056/NEJM199010253231710).

White, Adrian, and Katja Schmidt. 2005. 'Systematic Literature Reviews'. Complementary Therapies in Medicine 13(1):54–60. doi: 10.1016/j.ctim.2004.12.003.