



## Type 2 Diabetes Mellitus and what matters to patients the most when it comes to self-management outcomes

### Introduction

Most people over 65 years live with one or more chronic health conditions. Management of these conditions accounts for a significant portion of healthcare costs today: somewhere between 70% and 80%\*.

Patients living with chronic conditions mostly manage their condition themselves, at home and in the community, often helped by family or other informal carers. Providing patients with the right support for self-management and living well with a condition is an essential part of good chronic disease care and prolongs life expectancy.

Studies suggest that the right kind of self-management support can improve patients' health outcomes as well as bring value for society. However, today healthcare professionals and policymakers lack information about what self-management support activities (referred to as "self-management interventions", or SMIs further below) work best for different patients in different contexts. Patients with Type 2 Diabetes (T2DM) are usually referred to therapeutic education programmes upon diagnosis and this is an important part when it comes to SMIs.

COMPAR-EU is a project partly funded by the European Commission under its research framework programme "Horizon 2020". It started in January 2018 and will end in December 2022. The project aims to identify, compare, and rank the most effective and cost-effective SMIs for adults in Europe living with one of four chronic conditions: T2DM, Chronic Obstructive Pulmonary Disease (COPD), obesity and heart failure. **The project has developed 4 Core Outcome Set (COS) to guide self-management interventions in these diseases and will go on to develop an online decision-making tool for policymakers, researchers, patients, and the healthcare industry.**

What is a Core Outcome Set: a list of outcomes which patients and healthcare professionals have recommended that researchers should measure and report if they are undertaking a research study in a particular area. Prior to the selection of the COS, extensive literature search and analyses were undertaken by COMPAR-EU representatives.

### What new knowledge does this research bring?

A key strength of our COS is that it is strongly **based on patients' preferences** while also reflecting the perspectives of healthcare professionals and researchers. This means the COS should be quite **reliable and could be used in many different settings**. As a next step, the COS will be used to design an online tool to support decision-making by policymakers, healthcare professionals, developers of chronic disease management guidelines, patients, and their families on what are the most suitable SMIs in different contexts.

How was the COS developed?

First, COMPAR-EU researchers analysed the scientific literature and found a long list of different outcomes. We, the COMPAR-EU project consortium, then selected the most important of those outcomes in a two-round Delphi process. A Delphi process is a technique to find agreement between experts through a series of structured questionnaires and roundtable discussions.

The group voted **13 outcomes** to be a part of the final COS. Within these 13 outcomes, **6 are considered particularly important by all participants**, meaning very high support – 70% (or more) of the participants’ approval. On seven outcomes there were more mixed opinions in the group, however they are also part of the COS.

What are the outcomes patients consider most important?

The **outcomes most important** to patients in self-management of T2DM were:

**#Long-term complications #HbA1C #Hyperglycaemia #Hypoglycaemia event #Weight (management) & Quality of life**

You will find the full COS below in this document.

### The full core outcome set for T2DM

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T2DM Core Outcome Set	
Outcome:	Explanation:
Long-term complications	There are five major long-term effects of diabetes mellitus: 1. specific eye complications including potential blindness; 2. kidney disease that may lead to kidney failure; 3. neuropathy with risk of foot ulcers and/or foot amputation; 4. Charcot joints/Charcot foot; and 5. dysfunction of the autonomic nervous system, including sexual dysfunction. People with type 2 diabetes are also at increased risk of heart disease, arteries and veins blockage, and brain blood supply (cerebrovascular) disease.
HbA1C within recommended limits	Higher amounts of glycated haemoglobin indicate poorer control of blood glucose levels. HBA1C is a test that measures average blood sugar levels over 2-3 months. People with diabetes need to have this regularly monitored to see if the condition is well controlled.
Decreased time spent in Hyperglycaemia	Hyperglycaemia or an excess of glucose in the bloodstream. For the specific measure it must be individualised. For individuals living with diabetes mellitus, decreased time spent in a state of hyperglycaemia is better, as this prevents damage to parts of the body such as the eyes, nerves, kidneys, and blood vessels.

<b>Lack of Hypoglycaemia event</b>	Hypoglycaemia event or low blood sugar level (for the specific measure it must be individualised). None or fewer hypoglycaemia events (for certain types of medication).
<b>Weight (management)</b>	1. Weight loss: Reduction in weight. 2. Stable weight: Being able to keep a balanced weight. 3. Waist size: A decrease in waist circumference.
<b>Improved Quality of Life</b>	Quality of life (with a special focus on being able to perform usual activities, burden of treatment, mobility, copy with pain or discomfort, happiness and self-esteem). Including but not limited to diabetes-specific quality of life measures.
<b>Participation and decisions making</b>	Feeling able to participate actively in her/his own care (as much as s/he wishes). Engaging in self-management you must be motivated as it is core elements of self-management.
<b>Self-management abilities</b>	Skills and abilities with a special focus on 1. self-efficacy, 2. monitoring of one's own health and symptoms, 3. Knowledge needed to self-manage effectively and 4. Health Literacy.
<b>Self-management behaviours</b>	Actions with a special focus on taking medication or other treatment as advised (adherence), smoking control, dietary habits, and physical activity.
<b>Life expectancy</b>	Life expectancy with a special focus on number of healthy years lived.
<b>Experience of care</b>	Experience of care with a special focus on care satisfaction by patients.
<b>Scheduled care</b>	A decrease in scheduled care visits.
<b>Unscheduled care</b>	Decrease in or having no unscheduled care at all measured by the number of unplanned or emergency visits/admissions.
<b>SUPPLEMENTARY OUTCOMES*</b>	
<b>Caregiver knowledge</b>	Caregiver's knowledge of the health condition and diagnosis, treatment, and other aspects such as lifestyle and healthy choices.
<b>Blood pressure (control)</b>	Lowering of high blood pressure (hypertension) or needing to take less blood pressure medication.
<b>Impact on health care costs for the healthcare system</b>	Cost savings for the healthcare system as a result of the self-management intervention.
<b>Value for money of the self-management intervention (healthcare returns)</b>	The ideal combination of whole-life cost and quality (or fitness for purpose) to meet the user's requirement. It can be assessed using the criteria of economy, efficiency, and effectiveness.

\*Supplementary outcomes are outcomes which were viewed as secondary in terms of importance to patients, researchers and healthcare professionals.



**Background:** Chronic conditions affect over **80% of people above 65 years**. Also, between **70% and 80%** of healthcare costs arise from chronic disease management. The literature suggests that an **appropriate selection** of SMI outcomes is **essential** if research is to guide decision-making and inform policy. SMIs can improve clinical and societal outcomes in chronic conditions as well.

**What is a self-management/self-care:** self-management is defined as `what individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of healthcare professionals. It includes but is not limited to *self-prevention, self-diagnosis, self-medication* and *self-management* of illness and disability.

The project partners are the [European Patients' Forum](#); [Avedis Donabedian Research Institute](#) from Spain; [Institute for Medical Technology Assessment](#) from the Netherlands; [Netherlands institute for health services research](#); [OptiMedis AG](#) from Germany; [University of Ioannina](#) from Greece & [Sant Pau Research Institute](#) from Spain.

**What is a Lay Summary:** A lay summary is a brief summary of a research project that is used to explain complex ideas and technical and scientific terms to people who do not have prior knowledge about the subject. They are important not only for patients but also for lay persons and non-specialist medical professionals.

**What is a Delphi Process:** A technique which seeks to obtain compromise and agreement on the opinions of experts on a temporary panel, through a series of structured questionnaires and roundtable consultations.

**Who chose the T2DM COS:** Outcomes were prioritised in a two-round Delphi Process by patients and patient organisation representatives, researchers and healthcare professionals from around Europe in Berlin in 2018.

**What new knowledge did this research bring:** A key strength of COMPAR-EU COS is that they are strongly based on patient preferences while also reflecting the perspectives of clinicians, researchers and civil society representatives. We are confident that the COS and the supplementary outcomes reflect the preferences of all key stakeholders. Therefore, the resulting COS might be applicable with context adaptation to wide type of settings across Europe, and even worldwide.

### **More information needed?**

Please contact Mr. Lyudmil Ninov, EPF Senior Programme Officer by email: [lyudmil.ninov@eu-patient.eu](mailto:lyudmil.ninov@eu-patient.eu) or by telephone: + 32 2 274 08 67. You can also visit the project website: <https://self-management.eu/>

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