



Policy Stakeholder Views on the EU Health Data Space (EHDS)

Position of the Obesity Policy Engagement Network - EU (OPEN-EU) on the European Health Data Space (EHDS), prepared in January 2022 with the purpose of opening further dialogue with EU institutions and national entities towards leveraging the EHDS to address obesity as an NCD. This statement was drafted on the basis of input from OPEN-EU Members. It should be considered in conjunction with the other submissions of OPEN-EU Partner organisations as part of the stakeholder consultation process, as well as within the context of TEHDAS.

Summary

THE EUROPEAN HEALTH DATA SPACE, AND WIDER EU DIGITAL AGENDA, ARE CRUCIAL TO ENSURE THE LONG-TERM RESILIENCY OF HEALTH SYSTEMS AND TO LOWER THE PREVALENCE AND SEVERITY OF OBESITY AND ITS COMPLICATIONS.

THE CORE CHANGE NEEDED TO ENSURE PEOPLE LIVING WITH OBESITY CAN BENEFIT FROM EHDS IS THE URGENT NEED FOR NATIONAL AND PAN-EUROPEAN INFRASTRUCTURE TO BE INITIATED TO REFLECT THE EUROPEAN COMMISSION'S RECOGNITION OF OBESITY AS A CHRONIC RELAPSING DISEASE. THIS INCLUDES THE NEED FOR MEANINGFUL DATA COLLECTION PLANS, ACCURATE DIAGNOSIS OF OBESITY, AND SUPPORT FOR NATIONAL INITIATIVES.

Stakeholder Position Overview

The Obesity Policy Engagement Network - EU (OPEN-EU) welcomes the ambitions expressed by the European Commission in establishing a European Health Data Space (EHDS) to promote better exchange and access to health data for both primary and secondary usage.

The EHDS initiative represents a significant step towards the integration of health data across the European Union, aiming to leverage the full potential of digital health, provide high-quality healthcare, and reduce inequalities and thereby providing a strong foundation for health system resilience in a post COVID era.

The [Partner organisations](#) representing patient and consumer rights, academia and healthcare (biomedical societies included), Health Regions and health economic actors who together shape OPEN-EU aim to contribute to this initiative and ultimately better health outcomes for people living with obesity across Europe.

The constituencies of each OPEN-EU Partner organisation advocate for an EHDS which enables obesity to be addressed as a major non-communicable disease in line with the European Commission's own policy briefing which categorises obesity as not only a chronic disease in its own right, but also as a gateway NCD to other major and EU prioritised NCDs:

“Pre-obesity (overweight) and obesity are medical conditions marked by an abnormal and/or excessive accumulation of body fat that presents a risk to health ([WHO 2019](#)). Obesity is a chronic relapsing disease, which in turn acts as a gateway to a range of other non-communicable diseases, such as diabetes, cardiovascular diseases and cancer.”

SOURCE: [Obesity prevention | Knowledge for policy \(europa.eu\)](#)

Governance - an opportunity to address GDPR and data flow to the right people at the right time

While overall OPEN-EU Partner organisations are aligned with the broad objectives outlined in the EHDS, we would like to emphasise the need to move towards a more **person-centred, value-based healthcare systems approach**, which would allow for improved resource allocation, faster and easier identification of high impact interventions, efficient resources expenditure, and ultimately improved health outcomes and well-being for healthcare system users; not least the conservatively estimated 59.3% of Europeans living with pre-obesity (overweight) or obesity.

The EHDS provides a perfect opportunity to provide a framework to design, manage and evaluate such data for both primary and secondary usage as well as pivotally aid informed policymaking at all levels.

As such, OPEN-EU Partner organisations advocate as follows in regard to governance aspects of the initiative:

- The **EHDS establishes and employs a common understanding and related vocabulary and usage for health data** - especially in the case of obesity where we recommend the European Commission's text and WHO definition as a starting point (see above).
- The initiative takes into account the **need to meaningfully engage Regions** who often are responsible for the delivery of healthcare and digital services across the EU.
- The initiative **takes into account access to data for all stakeholders who can have an impact on health outcomes along the continuum**; across disciplines, stakeholder groups and economic sectors.
- The initiative also takes into account the need for **digital health literacy and engagement** of all stakeholders to ensure transparency and the ability of all stakeholders to partner for health outcomes.
- It is essential to **empower healthcare professionals** to capture a wide range of meaningful patient data to make an accurate diagnosis and encourage patients to continually record their own data over the long term, bearing in mind that obesity is a relapsing disease.
- **Patient and citizen access to their own health data** across treatment delivery sites and disciplines is crucial and has been shown to lead to direct improvement in their health markers and related outcomes. This is particularly important when addressing major NCDs such as obesity, as so much of the treatment and long-term management happens outside of primary care settings.

To allow obesity data within EHDS to flow seamlessly across borders, OPEN-EU advocates that specific challenges relating to recognising obesity as a disease will need to be overcome by putting in place essential practices, such as:

- Standardised data collection and sharing to avoid data localisation, reduce inconsistencies in experience when utilising health data, and enable seamless sharing of health information across borders.
- A harmonisation of metadata and related coding for all health professionals which is person first, non-stigmatising and free from discriminatory language.¹

¹OPEN-EU Obesity and COVID-19 Policy Position Statement. Page 4 [FINAL_OPEN-EU-Policy-Position-Statement-for-EU4Health-Programme.pdf \(obesityopen.org\)](#)

Data quality and interoperability - an opportunity to establish Obesity National Plans based on meaningful data

Specifically, we would highlight the major opportunity to address one of the significant gaps in building resilient health systems in the EU; namely integration of elements into the EHDS strategy, planning and implementation, through the lens of obesity as a chronic disease.

Obesity is currently the only major non-communicable disease (NCD) for which the following apply:

- There is **no systematic opportunity for early diagnosis or recording in an electronic patient record** of signs of biological/chemical markers or diagnosis of obesity.
- There is **no consistent standardised or federated data collection** beyond prevalence (conservatively estimated only using BMI).
- **No linkages are made within the National Health Surveys** or other EU level statistical data as to severity, long term progression, treatment or long-term management or control of this NCD.
- There is currently **no ongoing data interlinkage of the 230+ direct medical complications** (both physical as well as mental health) arising from the onset and untreated/unmanaged obesity, including 11 cancers, cardiovascular disease, 80% of Type 2 Diabetes and respiratory diseases.
- In the case of obesity – as with most NCDs, the majority of long term management and control is conducted outside of the primary care system through self-management interventions. Currently, there is **no harmonisation of these kinds of Real World Evidence (RWE)** included within health data or surveillance frameworks.

OPEN-EU Partner organisations therefore call for the inclusion of the following elements within the EHDS initiative related to **data quality and interoperability** of obesity along the life course to the benefit of 59.3% of Europeans already living with obesity:

- Ensure that **obesity is able to be recorded (beyond BMI)** as part of every electronic health record thus providing all stakeholders to benefit from both primary as well as secondary data usage perspectives.
- Embed obesity treatment and long-term management interventions (including self-management) into the [MyHealth@EU infrastructure](#)
- Ensure **interoperability of data across the 230+ medical complications of obesity** including cancers, cardiovascular diseases, respiratory diseases and diabetes.
- Efforts should be made to **collect and connect health and disease progression data for obesity and other chronic diseases** in a systematic manner to ensure clinical and policy decision-making is based on reliable information³.

Potential disease biomarkers for obesity which could form part of the electronic health record diagnosis tool kit include but are not limited to:

- insulin/insulin-like growth factor (IGF) axis and chronic low-grade inflammation which have been identified as major pathways.
- Ghrelin and specific [adipokines](#) such as leptin, [adiponectin](#) and [resistin](#)²

² Katharina Nimptsch, Stefan Konigorski, Tobias Pischon, Diagnosis of obesity and use of obesity biomarkers in science and clinical medicine, Metabolism, Volume 92, 2019, Pages 61-70, (<https://www.sciencedirect.com/science/article/pii/S002604951830266X>)

³ FINAL_OPEN-EU-Policy-Position-Statement-for-EU4Health-Programme.pdf (obesityopen.org)

- Mechanisms should be put in place whereby all data related to health outcomes can be of **“medical quality”**, **regardless of provenance**, e.g., patient reported outcomes, social prescribing sources etc.
- **Inclusion of real-world data** (including patient reported outcomes) in the scope of the EHDS would enlarge its potential and favour the advancement of research on the reliability of such data sources.

Infrastructure and technology

For EHDS to provide optimal value for people living with obesity, it will need to reflect the EC’s recognition that obesity is a gateway disease that contributes to the development of other non-communicable diseases, such as diabetes, cardiovascular diseases and cancer, as well as lower life expectancy and quality of life.

Obesity is a chronic, relapsing disease which **requires empowerment of patients and healthcare professionals to record, over the long term**, a wide range of meaningful patient data, in addition to BMI.

In order for the **224+ million people living with pre-obesity (overweight) or obesity** in the EU to optimally benefit from EHDS, it will be essential to ensure that a national and pan-European infrastructure is initiated to support the European Commission’s categorisation of obesity as a chronic relapsing disease. The EHDS represents a cornerstone to achieving this data infrastructure.

Within this context, OPEN-EU Partner organisations advocate for:

- **Registries on obesity along the continuum** to be established and interlinked with other NCD registries. This will be particularly useful in light of EU research gaps identified by the European Association for the Study of Obesity’s consultation of 32 organisations (including OECD and WHO Europe Region).⁴
- **Inclusion of obesity as one of the priority NCDs within the European Commission’s [Healthier together – EU Non-Communicable Diseases Initiative](#)** which will facilitate implementation of a digital pillar as for other NCDs.

⁴ [European Research Agenda: What’s Missing For Obesity - EASO](#)

About OPEN-EU

OPEN-EU acts as a collaborative policy coalition, which seeks to ensure that all relevant European institutional strategies and policies integrate measures that effectively help support people living with obesity at EU, national and regional levels and that the treatment of obesity as a gateway disease to type 2 diabetes, certain cancers and over 230 other complications of obesity. OPEN has identified four key pillars of action which are common across world regions.

View the OPEN-EU Call to Action [here](#):

1. **Awareness** of obesity as a chronic, relapsing disease
2. **Education** on obesity for health professionals, people living with obesity and all other actors who can have an impact on outcomes
3. **Sufficient** resources to sustainably achieve better outcomes for people living with obesity and hence stem the epidemic
4. **Establishment** of and access to multidisciplinary centres of excellence and care

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