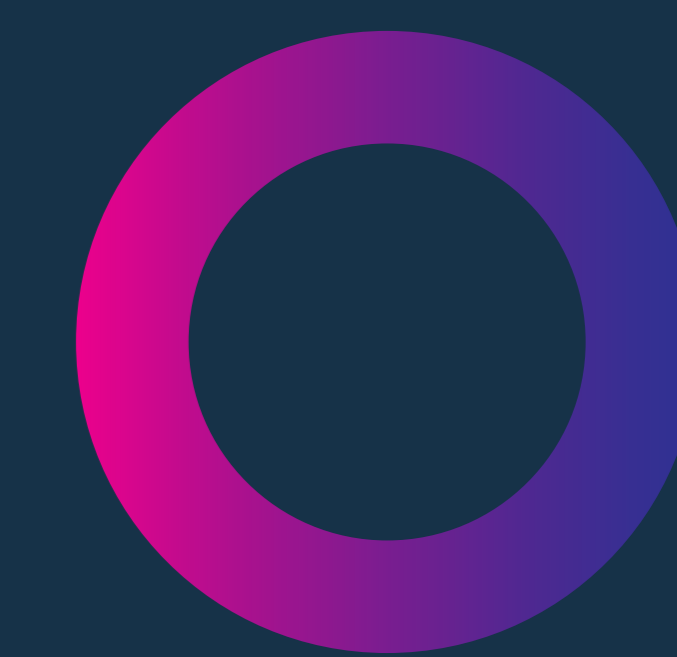


Identifying and Appraising Real-World Evidence Data Sources for the Overweight and Obesity Population Across the EU4 and the United Kingdom

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INTRODUCTION

- Obesity is a multifactorial disease in which accumulated excess body fat leads to negative effects on health.
- High body mass index (BMI) is a risk factor for non-communicable diseases, such as diabetes and cardiovascular disease, and can result in a substantial decrease in quality of life and life expectancy.
- As the prevalence increases across Europe, it is important to identify appropriate real-world data (RWD) sources for research in a real-world setting.
- Robust high-quality real-world evidence (RWE) will support optimal overweight and obesity treatment and management.¹

OBJECTIVES

This research aims to identify and determine the availability and suitability of RWD in overweight and obesity populations in order to generate high-quality RWE across Europe.

METHODS



A targeted literature review was performed to identify RWD sources in the published literature. RWD sources were also identified using data networks and data listing registries, including:

- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)²
- Heads of Medicines Agencies-European Medicines Agency (HMA-EMA) catalogues³
- B.R.I.D.G.E TO DATA⁴
- European Health and Data Evidence Network (EHDEN)⁵

Regional and national data sources were included in the review.

Administrative information, reported characteristics and access details were collected for each identified database from information available online or via prior experience working with the database.

RESULTS

One hundred RWD sources were identified across the EU4 and United Kingdom (UK): 10 RWD sources were identified in France, 23 in Germany, 30 in Spain, 9 in Italy and 28 in the UK. RWD sources consisted of electronic health and medical records (EMR) (n=42), claims and administrative databases (n=1), pharmacy databases (n=2), surveys (n=27) and cohort databases (n=28).

Figure 1. Overweight and obesity RWD sources by country

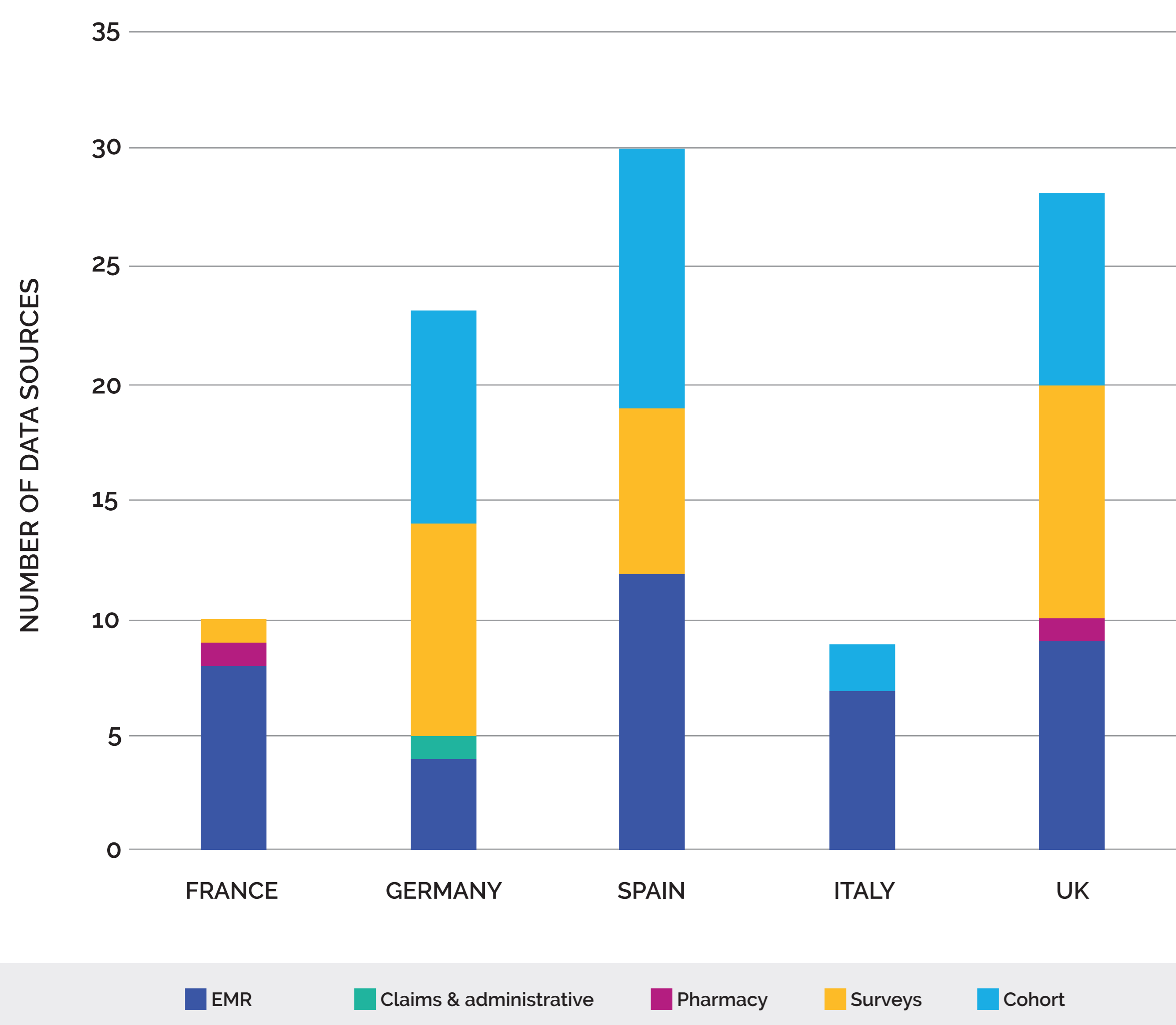


Table 1. Characteristics reported by identified data sources

| REPORTED CHARACTERISTICS | NUMBER OF DATABASES REPORTING CHARACTERISTIC | |
|----------------------------------|----------------------------------------------|----|
| Epidemiology | Obesity incidence | 86 |
| | Obesity prevalence | 92 |
| BMI | Actual BMI reported | 48 |
| | Ability to calculate BMI | 25 |
| | Linkage to other datasets required | 2 |
| Baseline Patient Characteristics | Age at diagnosis | 92 |
| | Sex | 89 |
| | Ethnicity | 29 |
| | Socioeconomic status | 52 |
| | Comorbidities at the time of diagnosis | 77 |
| Weight Loss Interventions | Dietary | 18 |
| | Exercise | 31 |
| | Behavioural | 21 |
| | Pharmacological | 62 |
| | Surgical | 46 |
| Clinical Outcomes | Treatment responses | 11 |
| | Mortality | 35 |
| Healthcare Cost and Resource Use | Inpatient visits | 41 |
| | Outpatient visits | 32 |
| | A&E services | 22 |
| | Costs associated with HCRU | 31 |

- Epidemiological factors of overweight and obesity are provided across all the datasets, with data owners capturing the incidence or prevalence of the disease.
- BMI was reported in 48 of the datasets and could be calculated in a further 25 datasets, with these datasets providing height and weight.
- There was significant variation in the patient characteristics reported, with important and potentially contributing factors not reported by some data owners.
- A range of weight loss interventions were reported, often with datasets capturing multiple weight loss interventions within the database.
- Clinical outcomes were not widely reported across all the datasets, often due to the epidemiology nature of some of the databases.
- There was variable reporting for healthcare costs and resource use across most of the datasets.

CONCLUSIONS

- A vast amount of overweight- and obesity-related RWD exists across the EU4 and the UK. Electronic health and medical records are the most readily available data sources, providing both national and regional coverage, often also allowing for linkage to other databases.
- There are both in-country and significant between-country discrepancies in how data is recorded for the overweight and obesity population. This presents a substantial challenge for linking data sources within country and combining multi-country RWD. The variation in the way in which weight is reported is challenging, with less than half of the databases using the most commonly reported measure of BMI to understand whether a person is a healthy weight for their height.
- Consistency in RWD reporting for the overweight and obesity population is essential to tackle this epidemic. Therefore, we must advocate for standardised reporting for this population to provide reliable, valid and generalisable findings across the EU4 and the UK.

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DISCLOSURES

The authors are employees of OPEN Health or Novo Nordisk.