

Background

The progression of health systems towards universal coverage depends on appropriate resource allocation. This study aims to analyze the factors impacting payer perception of unmet need and the subsequent prioritization of diseases with an associated ‘lifestyle’ component

Methods

We identified therapies approved by the European Medicines Agency (EMA) for three ‘lifestyle’ related diseases: obesity, smoking cessation, and type 2 diabetes mellitus (T2DM). Additionally, despite its link to tobacco smoking, metastatic non-small-cell lung cancer (mNSCLC) was chosen as a control for high disease prioritization due to its acute nature and direct link to patient mortality and morbidity. All the available therapies for smoking cessation and obesity were included in the current research. However, due to the high number of available therapies in T2DM and mNSCLC, four and three therapies, respectively, were selected for these indications, based on guideline recommendation and routinary use. We selected a number of countries that represented different market archetypes, including cost-effectiveness (i.e., England, Sweden, Denmark, and Norway) and clinical-effectiveness (i.e., France, Germany) markets. Health technology assessment (HTA) reports for the selected therapies were retrieved and assessed for HTA agencies in the in-scope countries.

Results

- A total of 15 products were identified across the six countries (obesity, n=6; smoking cessation, n=2; T2DM, n=4; mNSCLC, n=3), which were registered with the EMA.
 - For obesity, 11 out of 36 potential* HTA reports were identified, with 6 (54%) positive decisions. The HTA reports stated that comorbidities were the primary treatment focus.
 - For smoking cessation, 3 out of 12 potential* HTA reports were identified, with 3 (100%) positive decisions. The HTA reports noted the direct relationship between tobacco smoke and comorbidities, and its role as a risk factor of non-communicable diseases.
 - For T2DM, 9 out of 24 potential* HTA reports were identified, with 9 (100%) positive decisions. Although HTA reports noted a stigma associated with the ‘lifestyle’ component of T2DM, products were broadly reimbursed due to disease complications.
 - For mNSCLC, 13 out of 18 potential* HTA reports were identified, with 11 (85%) positive decisions. Therapies in mNSCLC were mostly reimbursed due to the poor prognosis and high mortality.
- When comparing countries where the drugs had been assessed, all countries showed similar trends for positive decisions across conditions.
 - France was the country with most identified reports, followed by the UK and Sweden.
 - Norway and Denmark were the countries with the least identified reports, with no reports being identified on obesity, T2DM, or smoking cessation in any of these countries.

FIGURE 1. TOTAL NUMBER OF COMPLETED** HTA REPORTS AND POSITIVE DECISIONS ACROSS DISEASES

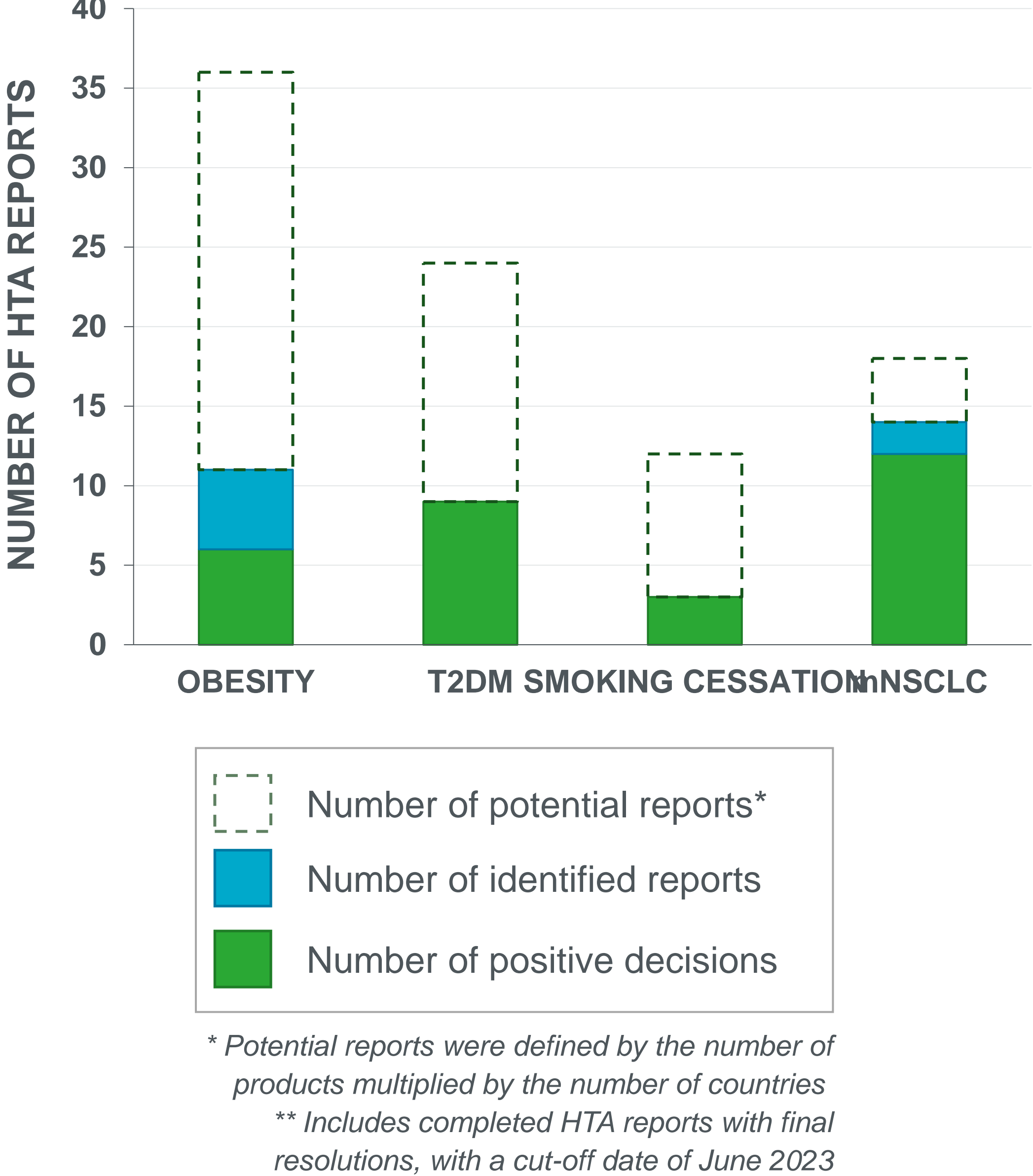


TABLE 1. TOTAL NUMBER OF HTA REPORTS AND POSITIVE DECISIONS ACROSS COUNTRIES

Country	Obesity (products: 6, potential reports: 36)		T2DM (products: 4; potential reports: 24)		Smoking cessation (products: 2; potential reports: 12)		Metastatic NSCLC (products: 3; potential reports: 18)	
	Identified reports	Positive decisions	Identified reports	Positive decisions	Identified reports	Positive decisions	Identified reports	Positive decisions
England, NICE	4	3	1	1	0	0	3	3
France, HAS	3	2	3	3	1	1	3	3
Germany, G-BA	1	1	2	2	0	0	2	1
Sweden, TLV	2	0	3	3	2	2	1	1
Norway, NOMA	0	0	0	0	0	0	3	2
Denmark, DMC	0	0	0	0	0	0	2	2

DHTC: Danish Health Technology Council; G-BA: Federal Joint Committee; HAS: National Authority for Health; NICE: National Institute for Health and Care Excellence; NIPH: Norwegian Institute of Public Health; mNSCLC: Metastatic non-small cell lung cancer; T2DM: Type-2 diabetes mellitus; TLV: Dental and Pharmaceutical Benefits Agency

Conclusions

Disease prioritization has historically been defined by diseases that have a direct, immediate, and quantifiable impact on payers’ budgets. Evidence-based unmet need value drivers that present the indirect complications and mortality associated with less-prioritized diseases (i.e., obesity) could support disease prioritization and funding allocating for therapies targeting those diseases. Moreover, early engagement with payers can provide insight into the level of evidence required to demonstrate the public health benefit, increasing the likelihood of reimbursement.