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OBJECTIVE

This observational study based on real-world data aimed to assess the incidence of herpes zoster (HZ) episodes among subjects aged ≥ 50 and at risk of HZ, namely the population that could benefit from the zoster vaccine according to the Italian Vaccine Action Plan (IVAP) 2017-2019. Therefore, the study intended to characterize these patients and to describe annual healthcare resources utilization and direct costs, in the perspective of the Italian National Health System (NHS).

METHODS

All analyses were carried out starting from the Fondazione ReS database that integrates, through record linkages, free filled drug prescriptions, hospitalizations and outpatient specialist procedures data - **Figure 1**. In 2013, patients aged ≥ 50 and at risk of HZ, as defined by the IVAP (at least with a disease/condition among the following: cardiovascular disease, chronic obstructive pulmonary disease, diabetes, immunosuppression), were identified. Subjects with an event of HZ in the previous year were excluded. Over two years after identification of patients at risk, new HZ episodes (incidence per 1,000) were recognized, by hospitalizations and brivudina prescriptions. For each incident subject, specific drugs consumption (antivirals and pain therapies), hospitalizations due to HZ and related direct costs, in the perspective of the NHS, were assessed during the first year after the new HZ event, both for the whole cohort and for the different at-risk subsets. According to Italian rules on GPs' payment, GPs visits were not included in this analysis.

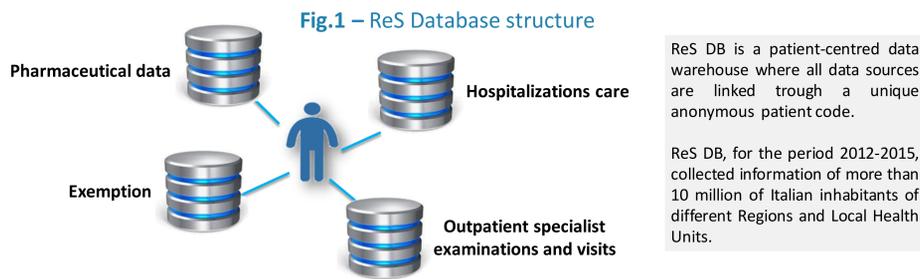
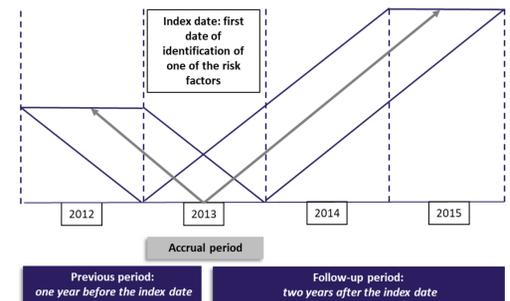


Fig.2 – Study design



RESULTS

Out of 12,562,609 beneficiaries, 1,004,705 (18.5% of subjects aged ≥ 50) patients at risk of HZ, and without a previous HZ event, were selected in 2013 - **Fig. 3**. During the two-year follow-up, **5,916 patients experienced a new episode of HZ (incidence: 5.9 per 1,000; mean age \pm SD: 74 \pm 10; 54.3% females)**. Significant **higher incidence rates** were found **for elderly patients** in comparison with younger ones, with the highest incidence for those aged 80-89 (7.2 per 1,000). Moreover, the incidence rate resulted significantly higher **for females** than for males (6.7 vs 5.1; $p < .05$). Among at-risk groups, the incidence rate **for immunosuppressed subjects** resulted the highest (6.9 per 1,000). The 87.1% of at-risk patients presented only one risk factor, the 11.9% two risk factors, 1.0% three and 0.08% four of them (groups are not mutually exclusive) - **Fig. 4**.

In the first year after the new HZ episode, **82.2% patients were treated with specific antivirals** (79.3% with brivudine, 4.5% aciclovir, 3.1% valaciclovir and 0.6% famciclovir), generating a **mean annual cost per patient treated of €106** (ranging from €105 in diabetes group, to €115 in immunodeficiency group) - **Fig. 5**. The 26.3% of subjects were treated with at least one prescription of pregabalin, tramadol, gabapentin, for the management of pain, generating a mean cost per patient treated of €94, with the highest cost for immunosuppressed patients (€155) - **Fig. 6**. Furthermore, **the 8.0% of subjects were hospitalized with a mean cost per patient hospitalized of €3,927** (ranging from €3,550 in COPD group, to €5,172 in immunodeficiency group) - **Fig. 7**. In the follow-up year every incident patient on average cost to the NHS €402, with the highest value for immunosuppressed patients.

Fig. 3 - Selection and characterization (by risk factor, gender and age) of the cohort in 2013

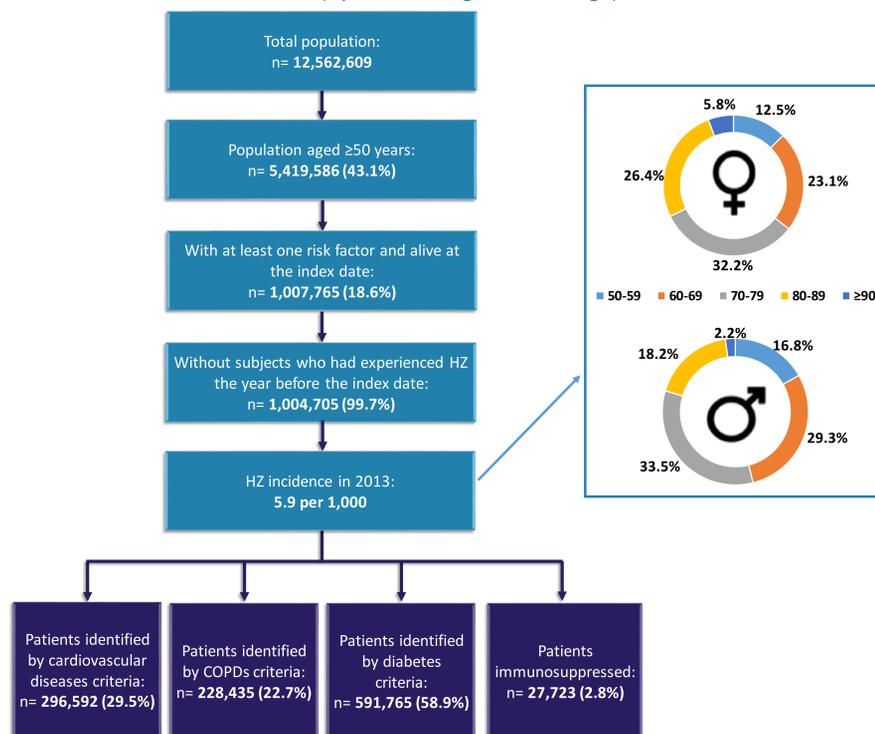


Fig. 4 - Breakdown of the study cohort according to the presence of one or more risk factors for the development of HZ

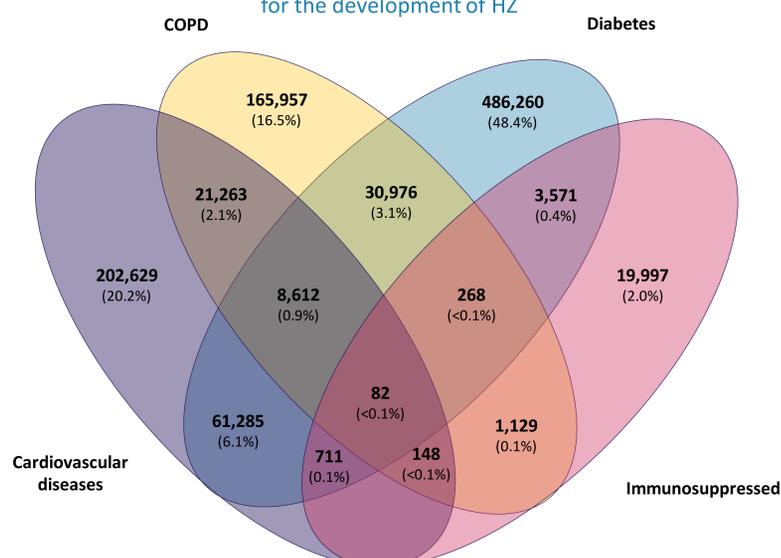


Fig. 5 – Specific drugs: percentage and cost of patient treated (€), by risk-factor group

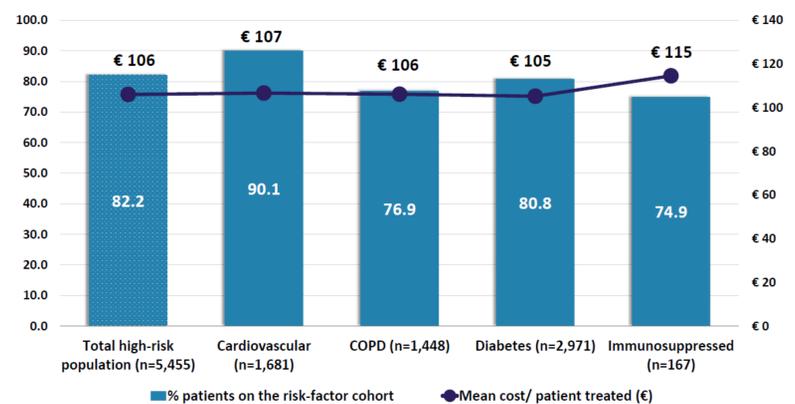


Fig. 6 – Pain therapy: patients treated and cost per patient (€), by risk factor group

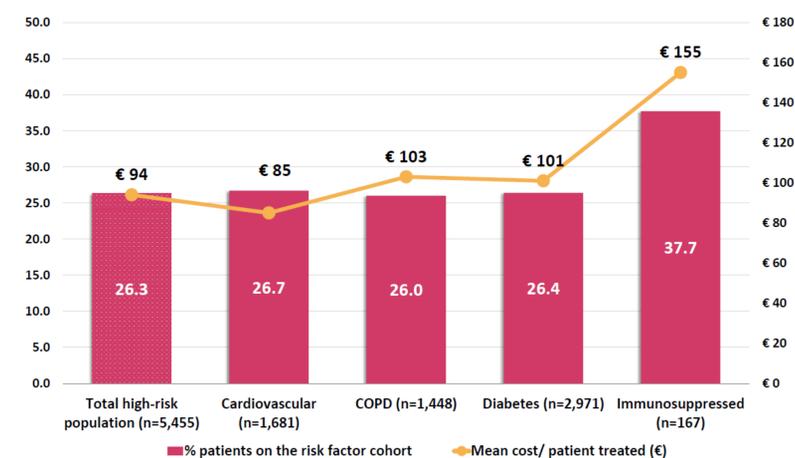
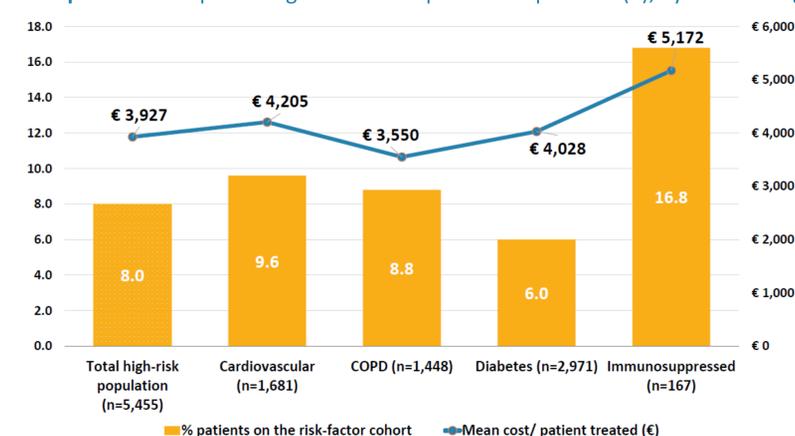


Fig. 7 – Hospitalizations: percentage and cost of patient hospitalized (€), by risk-factor group



CONCLUSIONS

This **real-world observational analysis** provided annual incidence (5.9 per 1,000) of HZ in subjects aged ≥ 50 years and with a disease/condition increasing the risk of HZ. It has been estimated that if the HZ vaccine was extensively administered to the target population, there should be an important decline in the incidence and a reduction of severity and duration of complications, e.g. ocular and PHN, as well as of costs in charge of the NHS. **The burden of HZ in the perspective of NHS was estimated**, too. All of these findings can help the health governance to **improve clinical decisions and economic positioning concerning HZ vaccination plan**.