



# Profile of spontaneous reports of Adverse Reaction Following Immunization from 2009 to 2011 in Portugal

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Adverse  
reactions

## Following Immunization

Public health  
protection



## Background

The study of adverse reactions following vaccination is a valuable tool for the maintenance of credibility of the government vaccination programs, to establish measures for risks minimization and for public health protection. In Portugal there is no study on vaccination safety therefore, identifying risks and disseminating this relevant matter is of main importance, essentially due the public opinion mistrust on the risk of vaccination.

The aim of this study was to characterize the adverse reactions following vaccination (ARFV) by analyzing the spontaneous reports registered in the database of the National Pharmacovigilance System (NPS) of Portuguese Authority Agency (Infarmed) from 2009 to 2011.

## Methods

Observational descriptive and cross sectional study, based on the Individual Case Safety Report (ICSR) submitted to the NPS. The ICSR were selected based on the reception date, between January 1st of 2009 and December 31st of 2011, with at least, one vaccine (J07) as suspected medicinal products, classified by Anatomic Therapeutic Chemical (ATC). ARFV were classified by the MedDRA dictionary.

## Results

During the studied period, 702 reports of ARFV were analyzed out of 6,622 of total reports, 32% of the cases were to individuals aged from 15 to 44 years, 67% were females. From 702 reports, 51.0% ARFV were serious, there were no deaths. The most commonly reported cases were general disorders and administration site conditions (43%), neurological (15%) and skin and subcutaneous disorders (9%). A total of 739 vaccines were reported, 38.7% of which were influenza vaccine and 17% papillomavirus vaccine.

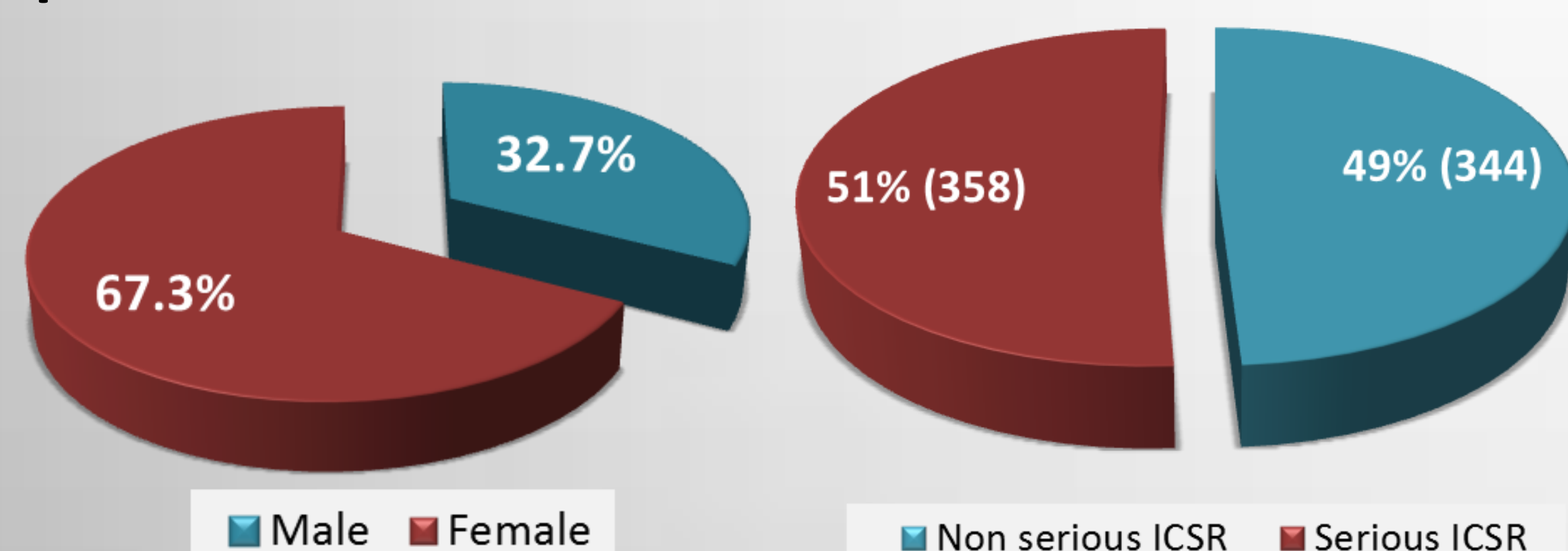


Figure 1. Vaccine ICSR per gender

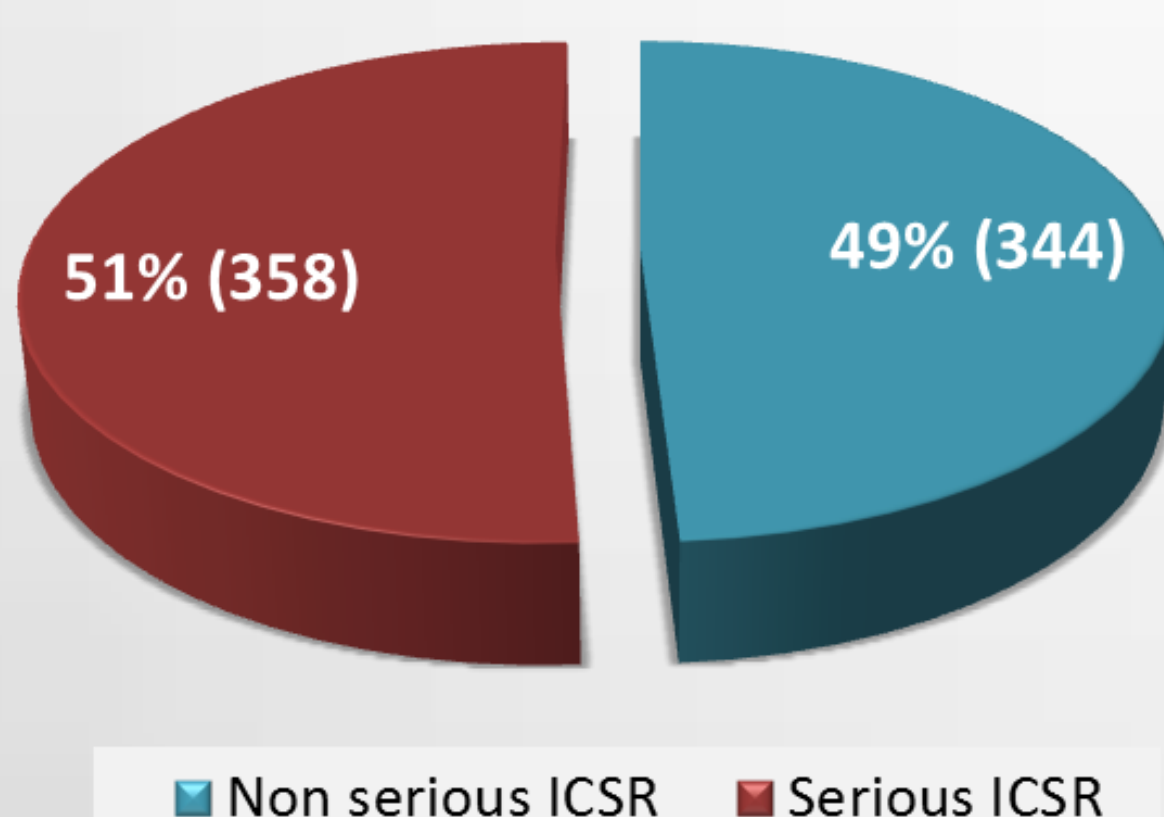


Figure 2. Spontaneous reporting per seriousness of the vaccine ICSR

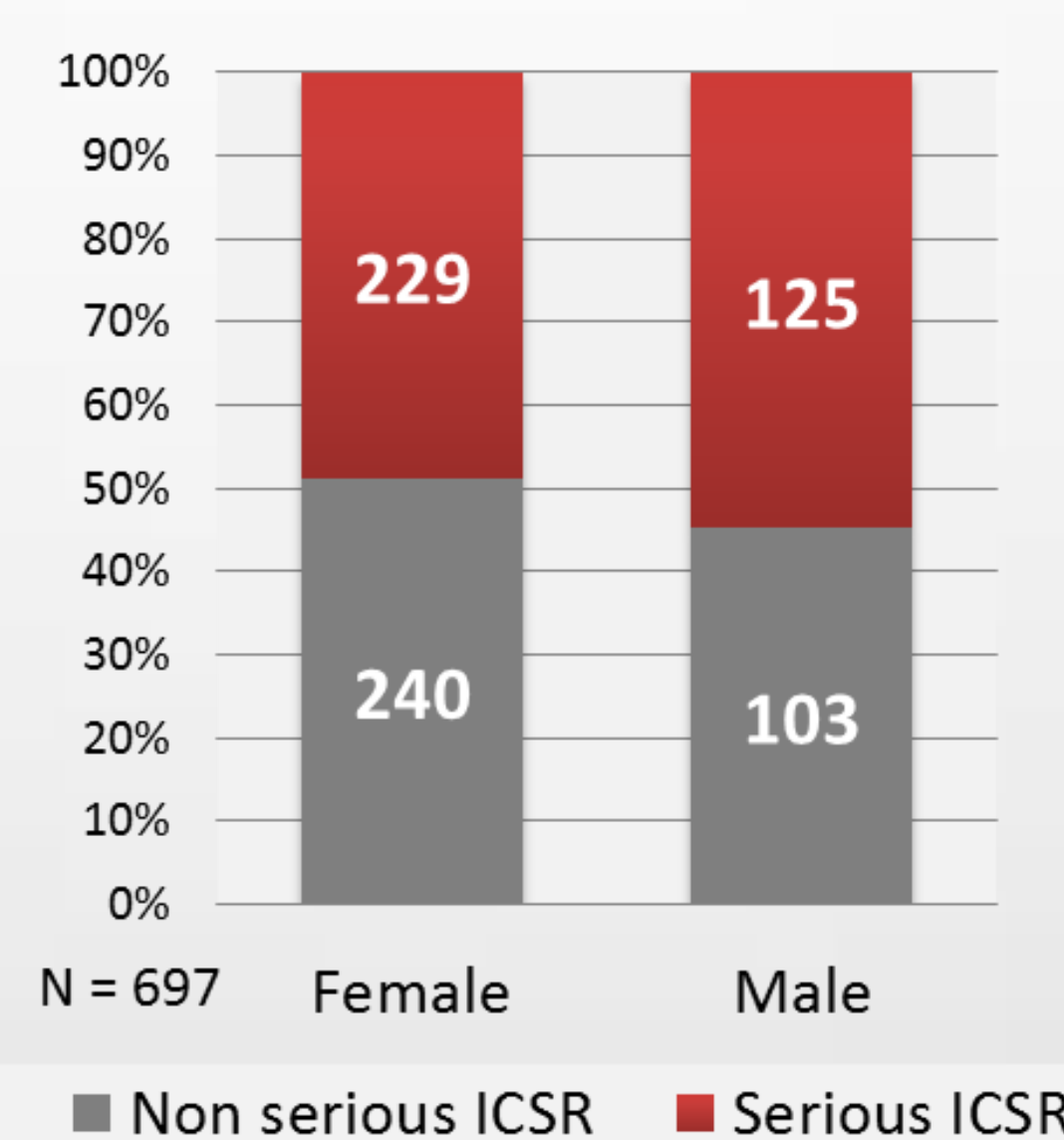


Figure 3. Percentage of serious vaccine ICSR per gender

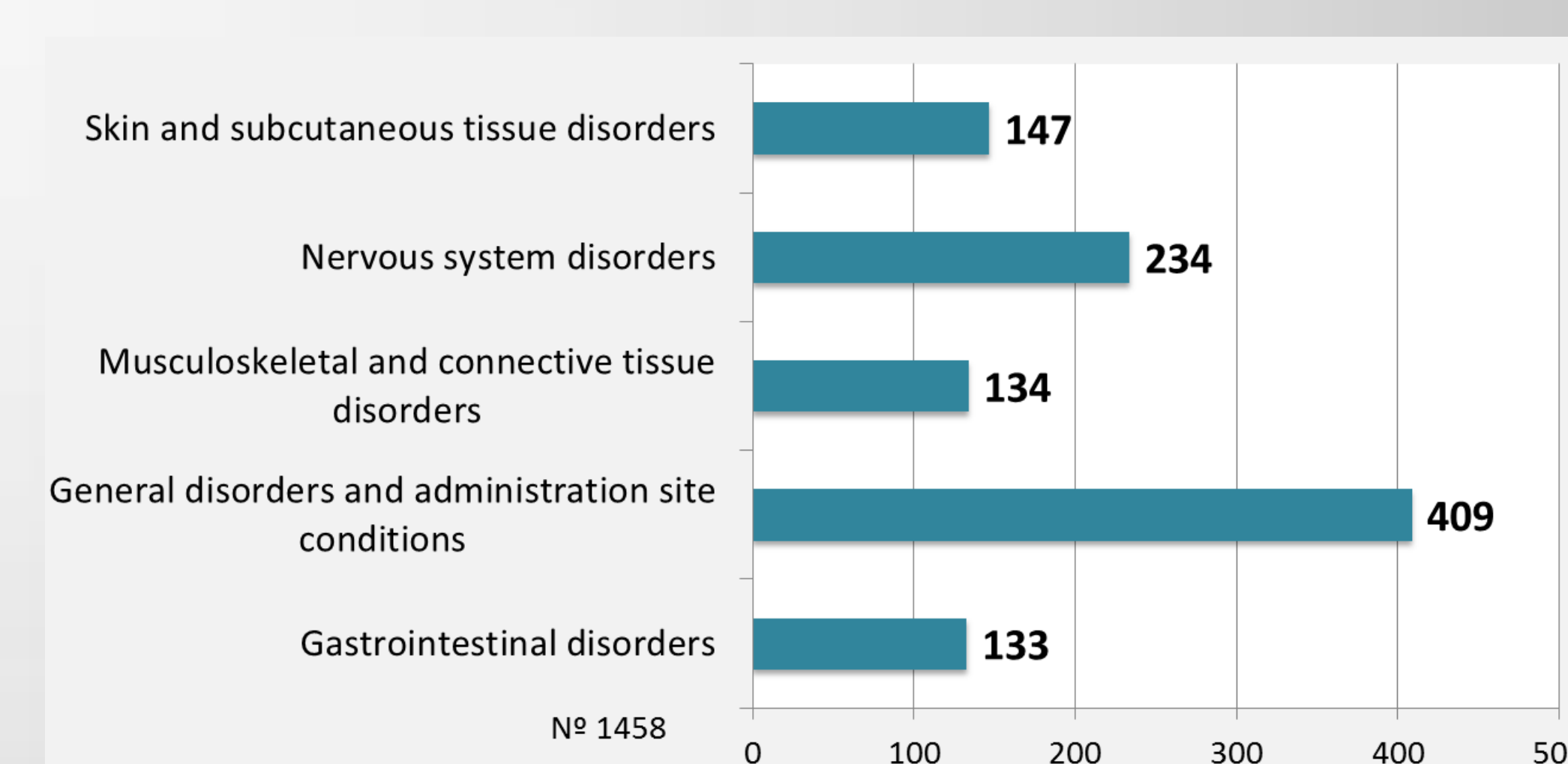


Figure 4. The top 5 system organ class most commonly reported

Table 1. The overview of spontaneous reporting per age and gender

Age	Female n (%)	Male n (%)	Total n (%)
< 1 years	29 (6.6%)	26 (12.3%)	55 (8.4%)
1 - 4 years	38 (8.6%)	41 (19.3%)	79 (12.1%)
5 - 14 years	90 (20.4%)	43 (20.3%)	133 (20.4%)
15 - 44 years	164 (37.3%)	47 (22.2%)	211 (32.4%)
45 - 64 years	88 (20.0%)	43 (20.3%)	131 (20.1%)
≥ 65 years	31 (7.0%)	12 (5.7%)	43 (6.6%)
Total <sup>1</sup>	440 (100%)	212 (100%)	652 <sup>1</sup> (100%)

<sup>1</sup> The total number of ICSR with gender and age of the affected people known, which was 652 (92.9%) of the total (702), there were 46 reports with no age and 4 with no gender.

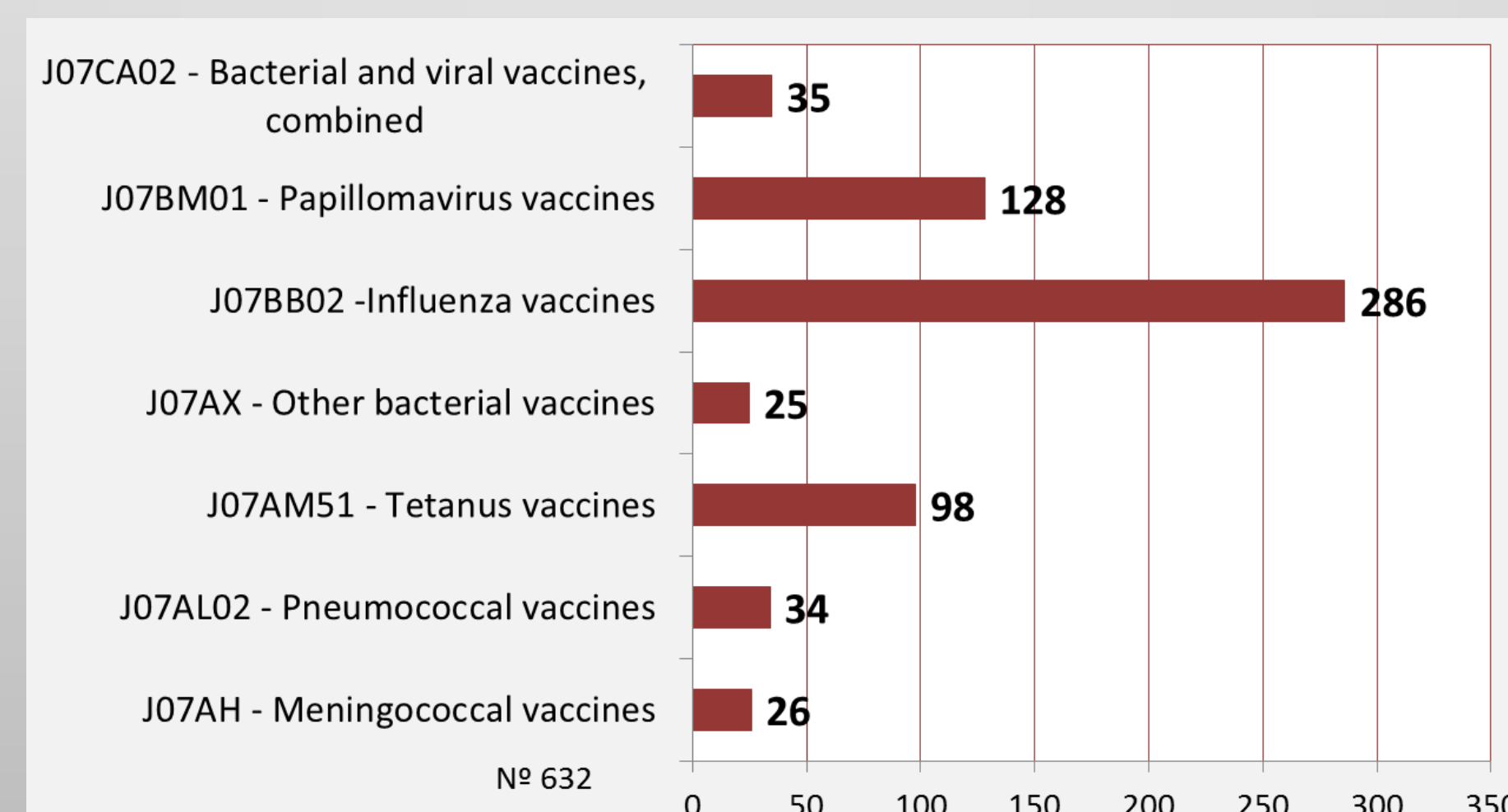


Figure 5: Top 7 ATC of the vaccines reported as suspected medicinal product

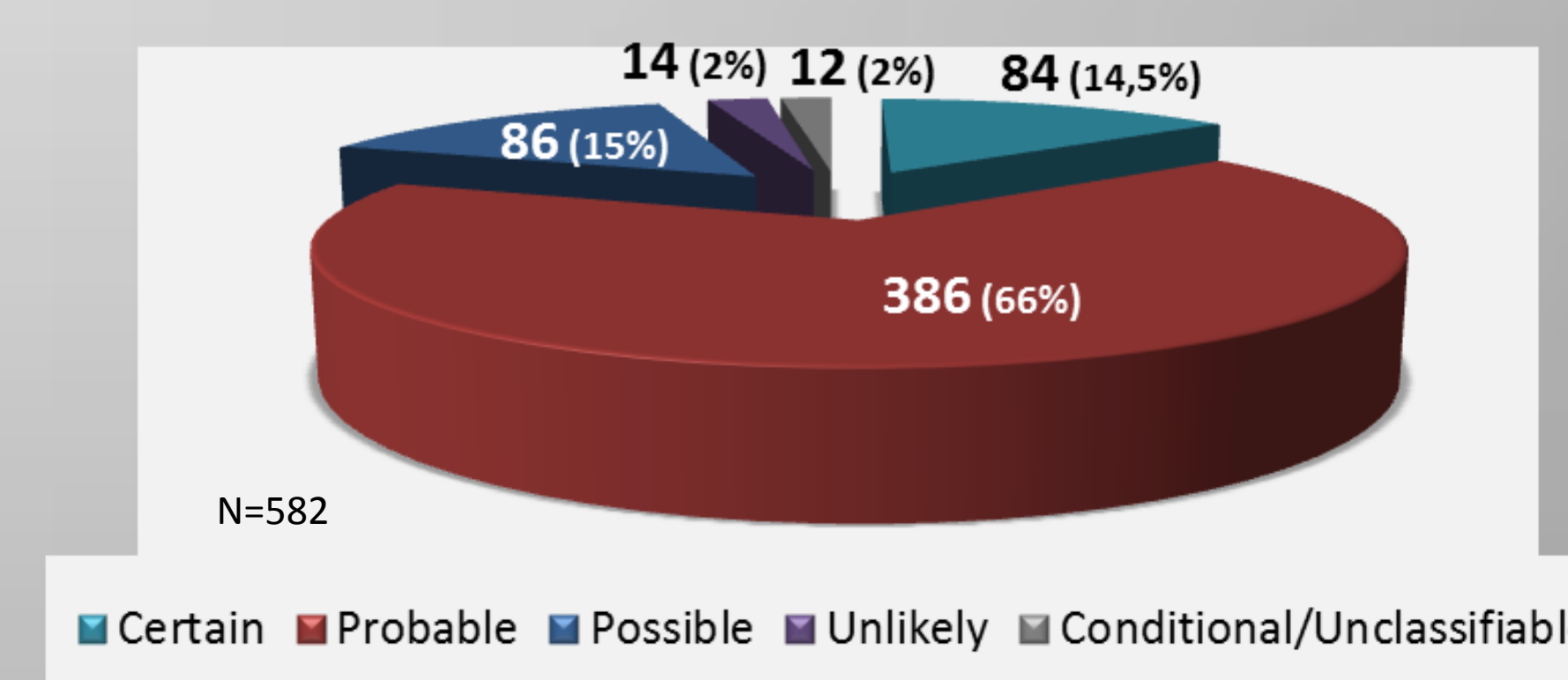


Figure 5: Vaccine ICSR per causality

## Conclusions

The results showed that Portugal has a similar frequency of ARFV as those described in the literature. This study showed that influenza vaccination is highly responsible for the occurrence of ARFV and the papillomavirus vaccine as well. The results suggest that Portugal should give special attention to the safety of vaccines, specially these two.