

Healthcare professionals' contribution on spontaneous reports of Adverse Reactions Following Immunization from 2009 to 2011 in Portugal

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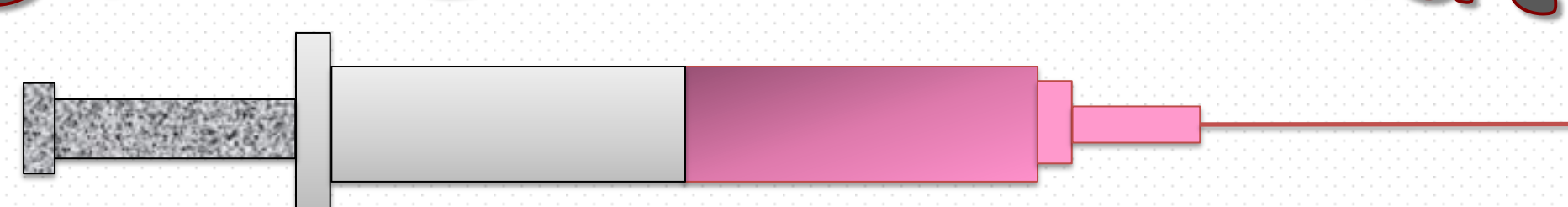
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Adverse reactions

Following Immunization

Public health protection



Background

The study of adverse reactions following vaccination (ARFV) 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. It is well known that healthcare professionals can be of main importance on the spontaneous reporting of adverse drug reactions (ADR).

The aim of this study was to characterize the different contributions of healthcare professionals on the pharmacovigilance of vaccine by analyzing the spontaneous reports of ARFV 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).

Results

During the studied period, 702 reports of ARFV were analyzed out of 6,622 of total reports. From those, 42% were received over the last 2 months of 2009, due to the massive vaccination campaign against the H1N1 influenza virus. The nurses were responsible for 56% (393) of the ICSR, physicians for 31% (218) and pharmacist for 7% (52). Only 2% reports were sent by consumers indirectly through marketing authorization holders, as by this time, patients weren't allowed to independently report ADR in Portugal. Physicians were responsible for 44% of the serious cases, nurses for 41% and pharmacists for 6%. The pharmacists reported the highest proportion of unexpected ARFV (62%), followed by physicians (38%) and nurses (21%). These results are not in accordance with the profile of ADR reports by healthcare professionals during the same period of time, as for all of the ICSR, pharmacists reported 23.3% (1,541) of ADR, while physicians and nurses notified 20.6% (1,364) and 8.6%(570) respectively.¹

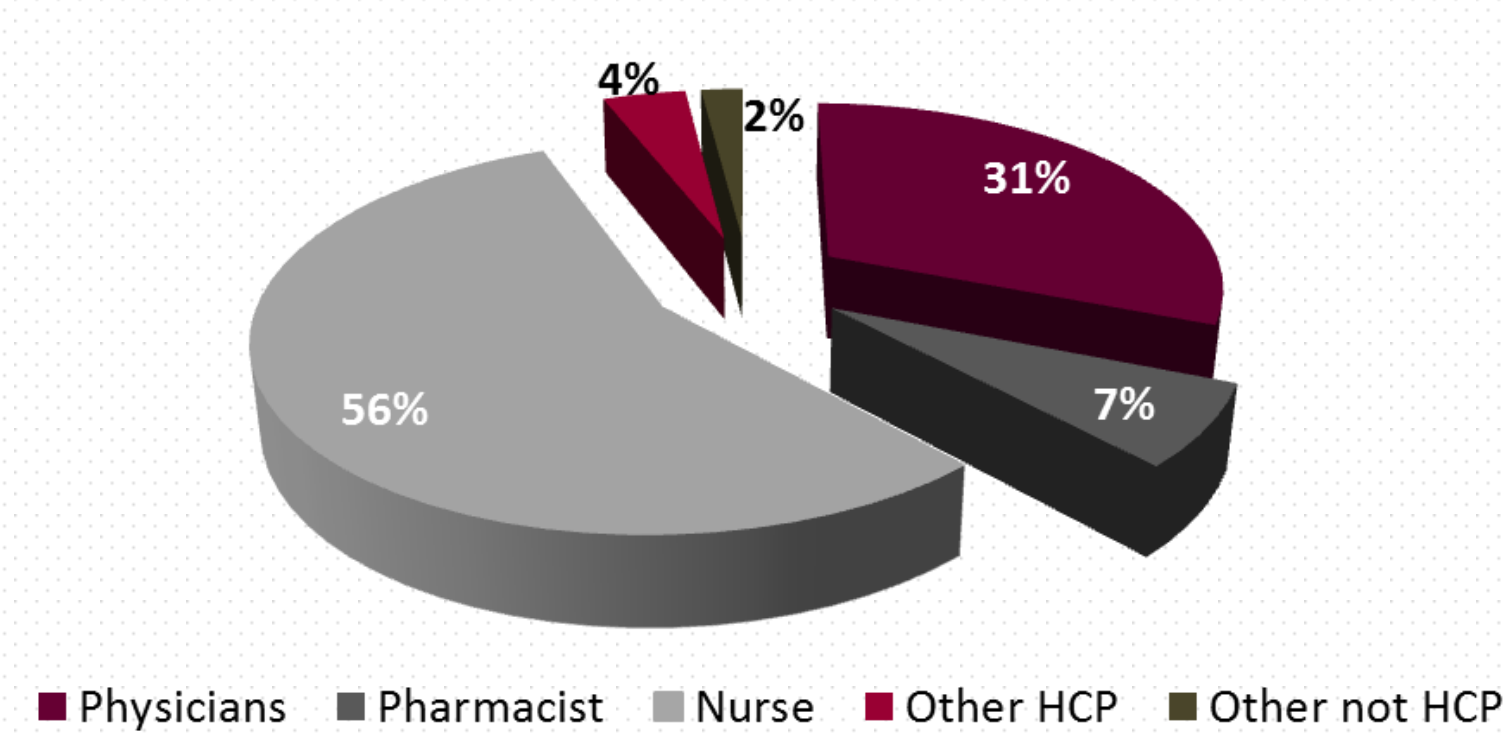


Figure 1. Profile of reporting per healthcare professionals

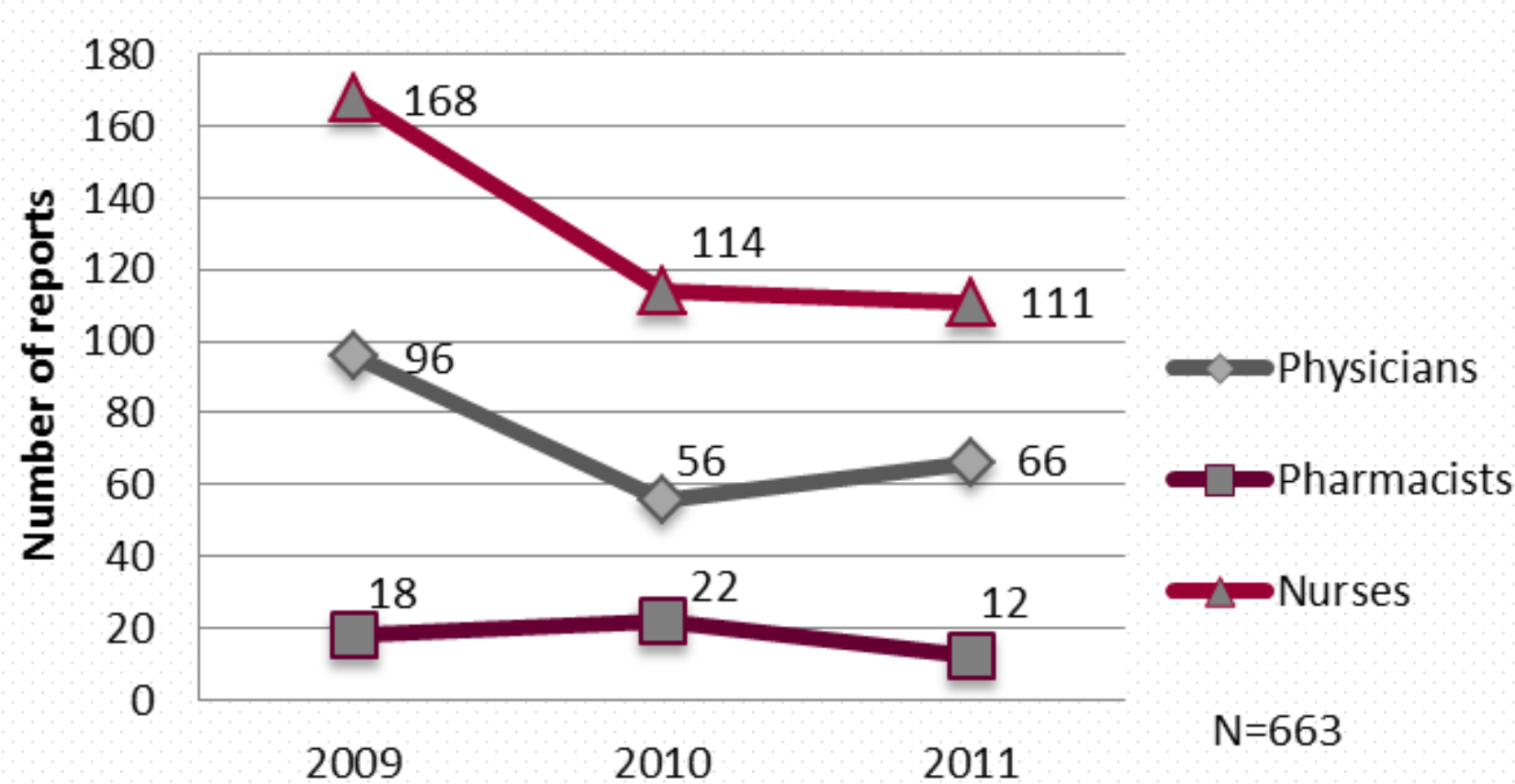


Figure 2. Profile of reporting per year and healthcare professionals

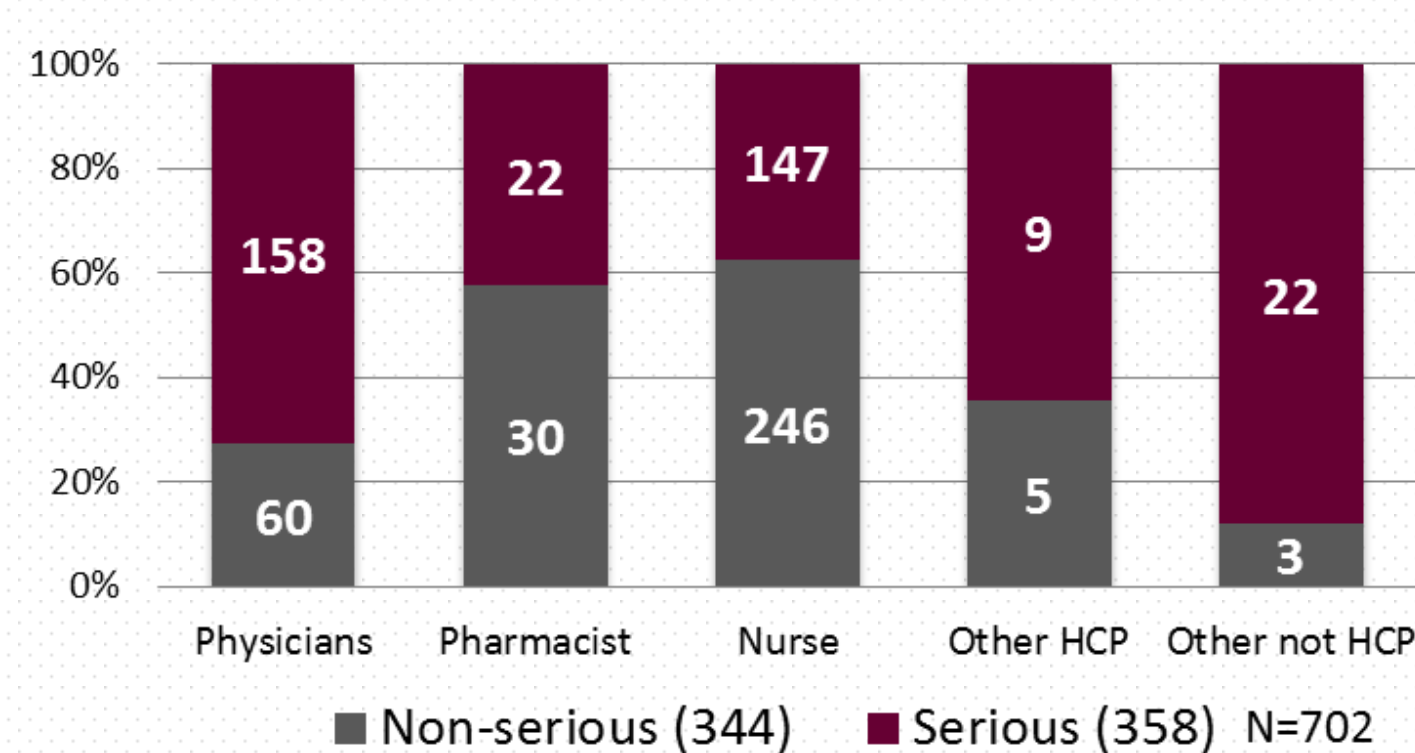


Figure 3. Percentage of serious reports per healthcare professionals

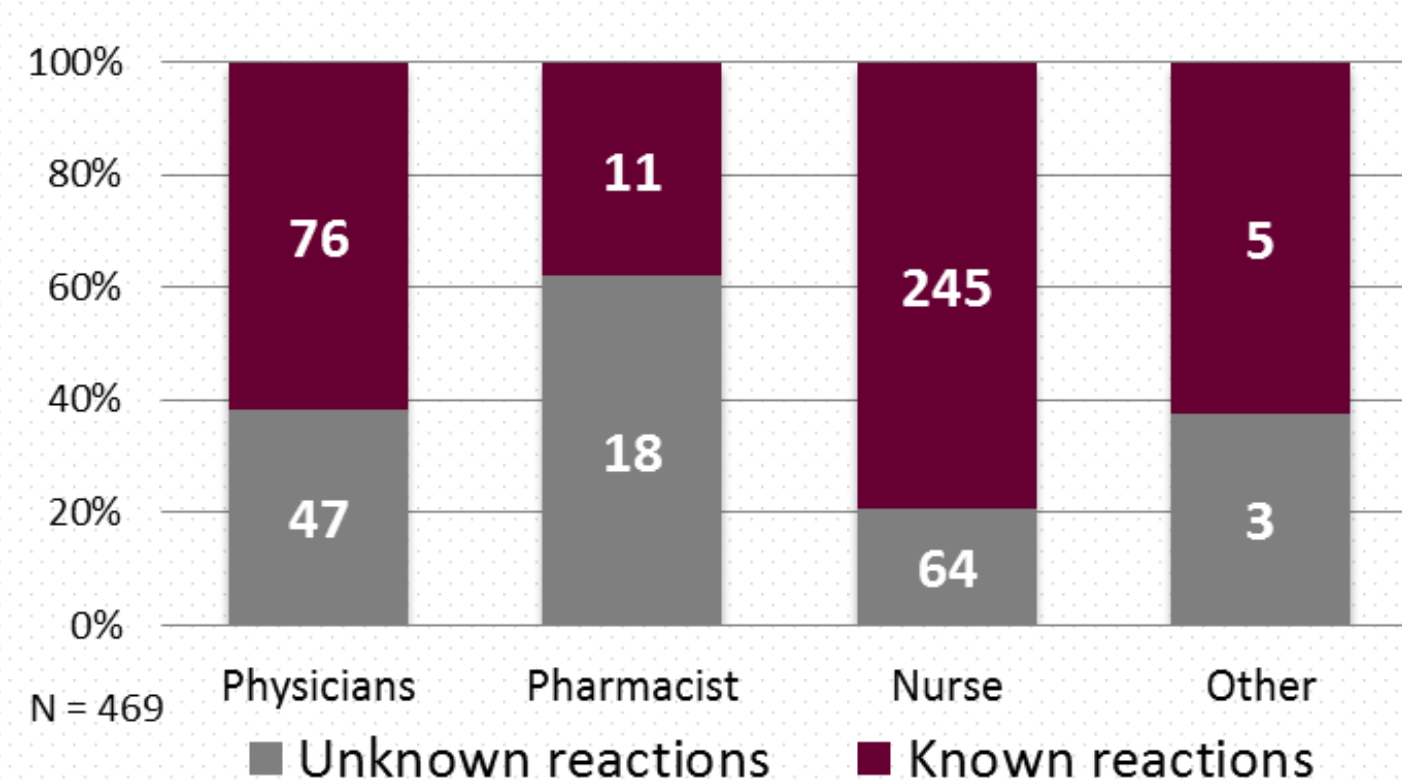


Figure 4. Percentage of unknown reactions per healthcare professionals

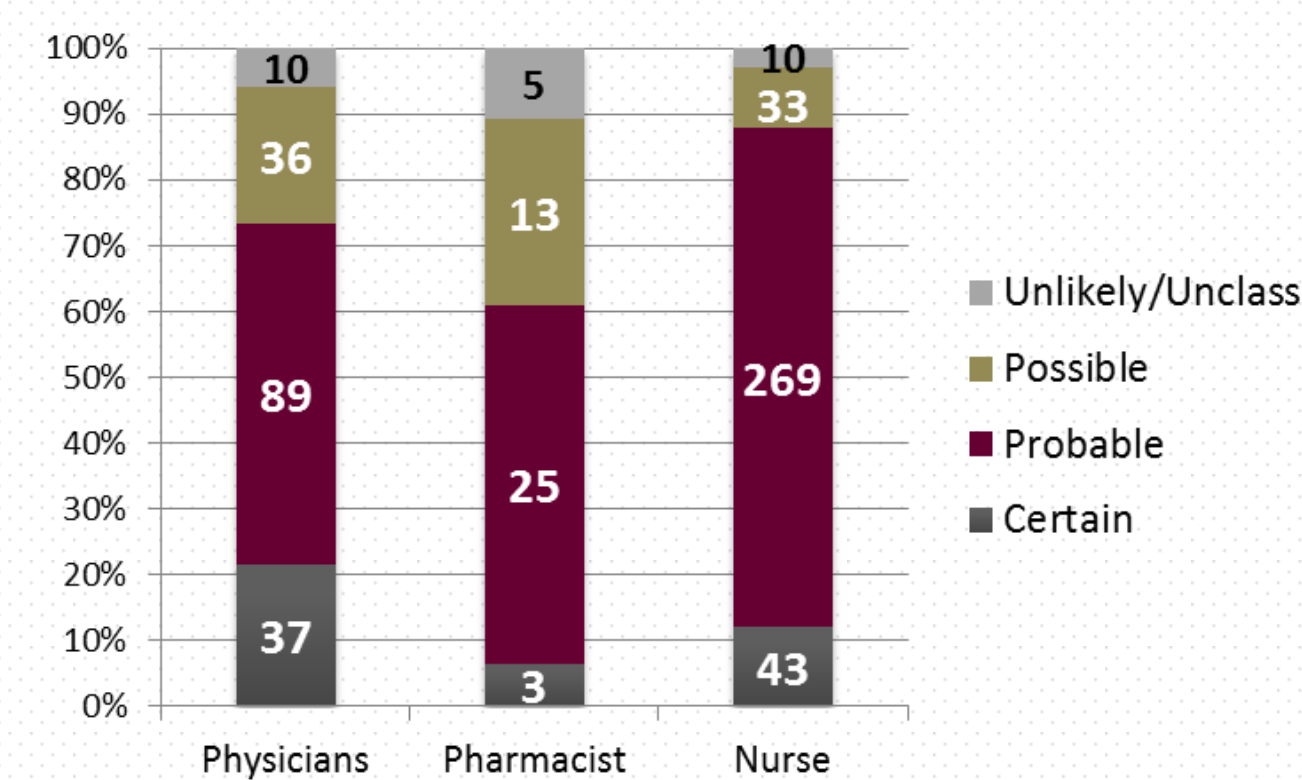


Figure 5. Percentage of causality per healthcare professionals

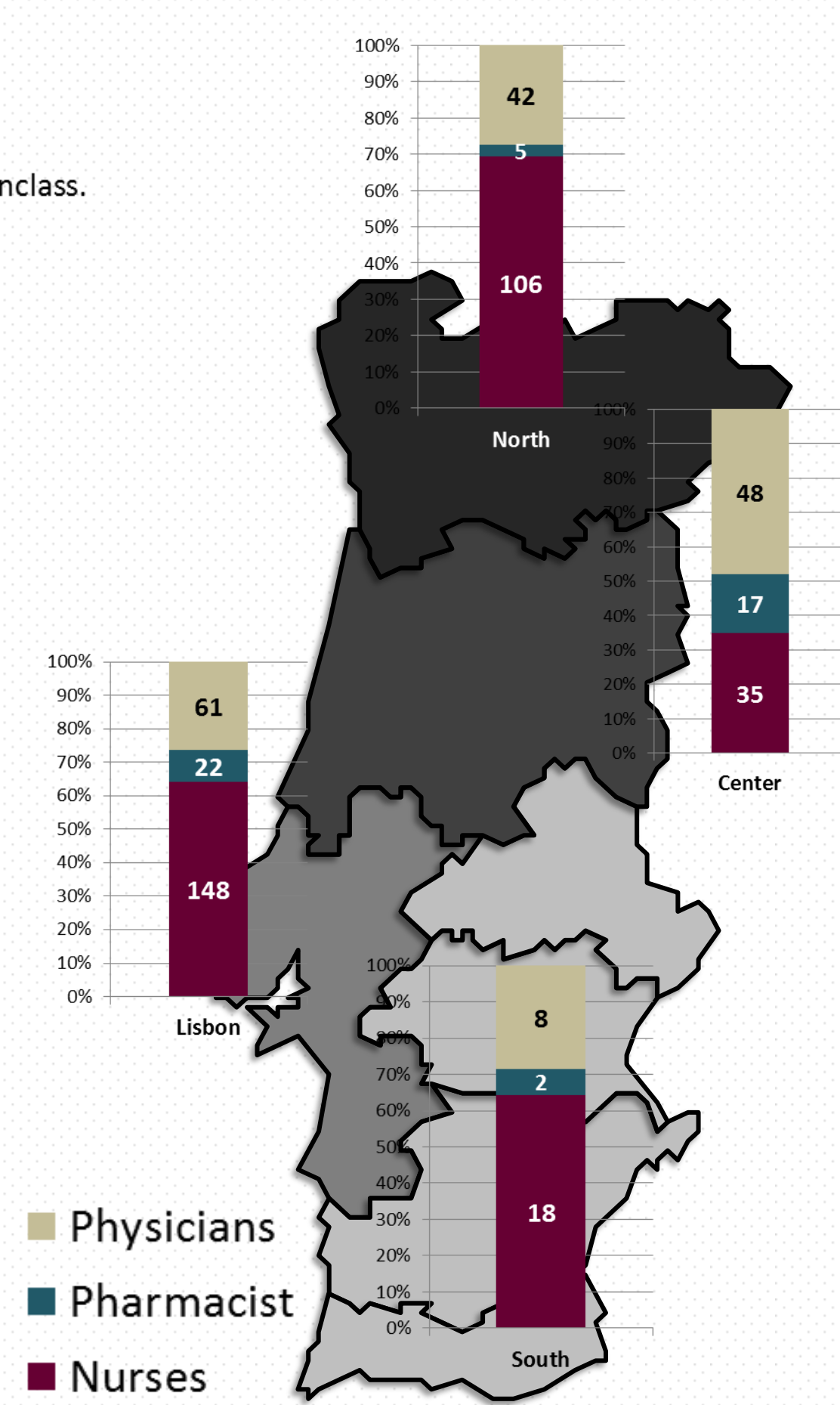


Figure 6. Percentage of healthcare professionals per Portuguese region

Conclusions

The study showed that, in Portugal, physicians and nurses were the main reporters of ARFV unlike what happens with other medicines. This role of the nurses was understandable because vaccines are mostly administered at Healthcare Centers by nurses.