

# Adult Immunization Board

**The Herpes Zoster example from Greece**

Sotirios Tsiodras

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# **National Immunization Committee, Greece**

## **Recommends inclusion in NAIS, im x 2 doses, April 2023**

- **First phase**

- Immunocompromised individuals  $\geq 60$  yrs
- Immunocompromised individuals  $\geq 18$  yrs w recurrent episodes of zoster

# Rationale

**will be published in public domain, 1559 words, 46 Refs**

- Includes baseline epi info, vaccine info, regulatory info (EMA) & SPC based on clinical trial results
- Provides estimates of efficacy for both vaccines in medical terms
  - 95% Cis, p values
- According to literature disease more severe & complications / hospitalization more frequent in ages  $\geq 65$  yrs

# Rationale

## spc info, detailed scientific language

- Includes baseline info, vaccine info, SPC info & regulatory info (EMA),  
clinical trial results, safety info
- Provides estimates of efficacy for both vaccines in medical terms
  - 95% Cis, p values

# Rationale

## Age criterion & severity

- According to literature disease more severe & complications /  
hospitalization more frequent in ages  $\geq 65$  yrs

# Rationale

## Incidence rate local studies, bias

- Cites limited epi info from Greece
  - **Tertiary care cross-sectional study 1995-2002**
    - 12.4 ‰, median age 64 yrs, m/ 63 yrs f, highest in >80 yrs
  - **Prospective surveillance data 2007-2009, in island of Crete, 1ry care network**
    - 1.4/1000 pt-yrs

# **Rationale**

## **Immunocompromised pts, 1 local study**

- **450 pts post kidney transplantation, f/u: 38 months**
  - **4.6% HZV episode - incidence 20.6 per 1000 pt-yrs, 10.3% hospitalization**
  - **no generalized dz, no deaths but... 48.7% post-herpetic neuralgia**
  - **Risk factors: age  $\geq$  60 yrs, history of VZV, anti-rejection Rx**

# **Rationale**

## **Cost-effectiveness studies, world**

- **Reference to USA, Japan, limited European data**
- **Acceptable cost-effectiveness**
  - **Mostly for RZV vs. no immunization**
  - **in people aged  $\geq 60$  yrs**
  - **Price much lower than the one vaccine will be offered in Greece**



# **Rationale**

## **Immunization guidance, other countries**

- **Germany, UK, Switzerland, Australia, USA, Canada**
- **Heterogeneity in recommendations**
  - **Type, age, high risk groups**

# **Rationale for final decision, no comparison**

## **Immunogenicity, duration, IC pts, cost-effectiveness**

- **RZV -> Better efficacy**
- **RZV -> Only vaccine to be administered in IC pts (BMT, RTx, Solid Ca)**
- **RZV -> Longer duration of protection**
- **Zoster severity / complication worse w ↑ age**
- **Cost prohibits general recommendation**

# National Immunization Committee, Greece

## Recommends only in IC, ZVL in others

- **First phase**
  - Immunocompromised individuals  $\geq 60$  yrs
  - Immunocompromised individuals  $\geq 18$  yrs w recurrent episodes of zoster
- Analytic tables w ICD 10 codes & IC meds w ATC codes

# National Immunization Committee, Greece

## Recommends inclusion in NAIS, im x 2 doses, April 2023

- Pts who are going to undergo immunosuppressive therapy
  - administer 1<sup>st</sup> dose **one month before the start of treatment**
  - 2<sup>nd</sup> dose administered **1-2 months after the 1<sup>st</sup> dose**
- Prophylactic antiviral treatment is not a contraindication
- Pts previously vaccinated w ZVL should be vaccinated w RZV after at least 5 years have passed since the vaccination w ZVL

# Problems

- ID society of Greece adapts & publishes online ACIP/CDC guidance
- Formal complaint from company
- Availability of ZVL ?
- Next phase when? Cost issues may affect rest of national schedule
- Communication issues, supporting statement using scientific language