BACKGROUND

- Italy was traditionally considered a Country with an intermediate prevalence for HIV infection, with HBsAg positivity ranging between 1.6 and 3.4% (with areas topping to 5.6%).
- HIV incidence and prevalence started to decrease during the 1980s, for the improvement of socio-economic conditions, the change in medical procedures, a better knowledge of local transmission routes and the availability in 1983 of a vaccine for key populations such as intravenous drug users (VDU), men who have sex with men (MSM), patients undergoing hemodialysis and healthcare workers.
- In 1993, the law n. 165 introduced mandatory HIV vaccination for all people born after 1979 through two different cohorts (Figure 1):
  - Born between 1979 and 1991: vaccinated at their 12th birthday;
- The rate of vaccination response is generally 90% to 95%, but 20 years after vaccination administration the coverage drops to 60%.
- In 1991, 40% of HIV-positive individuals who received the vaccine after HIV infection, the response rate is below 30% seven years after vaccine administration.
- According to the Ministry of Health, vaccination coverage in Italy has always been around 95%.

STUDY DESIGN AND METHODS

STUDY POPULATION
- ICONA Foundation Cohort is an observational Study that enrolls HIV positive subjects naïve to antiretroviral treatment from more than 50 Centers operating throughout Italy. Since 1997, more than 16,500 individuals have been included in the ICONA Study.
- Subjects born in Italy after 1979 with full serology for HIV available at ICONA enrollment (i.e. before antiretroviral treatment start) were included.
- Demographic, clinical and behavioral features were collected.

STUDY PURPOSE:
- Assess long term vaccination response in Italian horizontally infected HIV+ subjects who received compulsory anti-HBV vaccine in their childhood.
- Evaluate the proportion and risk factors for HIV breakthrough despite vaccination.

RESULTS (1)

- 1,145 subjects showed a protective anti-HBs value >10 IU/mL; thus, 70.3% resulted vaccine responder after a mean follow up of 18.1 years.
- 483 individuals did not show a protective anti-HBs value: 383 (24.2%) resulted negative for HBsAg, anti-HBs and anti-HBc, thus they could be eligible for re-vaccination;
- 90 (5.5%) showed a serology consistent with a contact with HIV before ICONA enrollment:
  - 12 (0.7%) were HBsAg+ → chronic infection;
  - 66 (4.1%) were anti-HBs+/anti-HBc+ → previous infection;
  - 12 (0.7%) presented an isolated anti-HBc+ → occult infection
  (also defined as “Phase 5” in the 2017 EASL Guidelines).
- 1,628 individuals were included: 88.7% males with a median age of 29 years (IQR 25-32) mainly belonging to the 1979-1991 cohort (Table 1).

CONCLUSIONS

- The failure to induce protective anti-HBs levels after vaccination demonstrates the need for a booster dose in this cohort.
- Being HCV co-infected, smoker and daily alcohol user are risk factors for HIV infection before ICONA enrollment.
- None of the HIV-related and behavioral features resulted associated with response to anti-HBV vaccination.
- Belonging to the 1979-1991 cohort resulted the only factor associated to anti-HBs level >10 IU/mL.
- Over the course of 29,343 years, cumulative incidence of any HBV infection (chronic, previous, occult) of the was 3 per 1000 patients/year of follow up (PYFU, 95%CI 2.5-3.7).

Table 3 - Factors associated with HBV acquisition before ICONA enrollment.

Acknowledgments – ICONA Foundation Study Group

- A d’Arminio Monforte, A Antinori, A Castagna, F Ceccherini, \textit{et al.}

REFERENCES

- **McMahon B**, et al. JID 2006.

Funding

ICONA Foundation is supported by unrestricted grants from BMS, Gilead Sciences, Janssen, MSD and VIV Healthcare.

Contact Information

Mail: health@icona.it
Address: AID 434 Quarto Cimiterale, Metropolitano Nigraio, viazz Coropale 5, Milan, Italy.